EXHIBIT LIST

1. Physician Letter
2. Physician Medical Report
3. Emails
4. Medical Exemption
5. PPE Chart
6. Dr. Waselenko Affidavit
7. Dr. Waselenko Addendum
8. Senator Johnson Letter
9. Pfizer FDA Approval

EXHIBIT 1

To the Staff, Administration and Board of the St. Elizabeth Healthcare system,

We submit this letter to express our strong objection to the COVID-19 vaccine mandate being forced upon the entire organization. We feel that true informed consent is being abrogated by the rush to push this experimental medical procedure upon us all regardless of medical, religious, or conscientious differences. There has been a lack of debate, dialogue, and charity towards dissenting opinions in the greater medical community which is now playing out here locally. The basis of our objections is detailed as such:

1. All current vaccines allow permissive infection and transmission of fully vaccinated individuals; therefore, they DO NOT "provide strong protection against unintentional spread" but may do the opposite due to a false sense of security in the vaccinated individual.
Natural immunity is at least equal to and likely superior to vaccine immunity, yet this has not been a part of the discussion for unclear reasons. A majority of healthcare providers in our system are declining the vaccine due to prior infection and already having sufficient immunity to COVID-19.

2. We acknowledge the majority of hospitalized patients in NKY currently are unvaccinated and that the vaccines to-date may be a helpful prophylactic treatment to reduce incidence of hospitalization in at-risk individuals. However, given the non-sterilizing properties of these vaccines, they will NOT lead to eradication of the disease, but rather induce selective pressure for development of variants with increasing vaccine resistance. We hope that future vaccines may be safely developed that are sterilizing to prevent infection and transmission.

3. Last year the flu vaccine, which has been studied for 78 years, was mandated by the system without much debate because the safety of the vaccination has been clearly established. This current mandate is not equivalent. These novel, gene therapy-based COVID-19 vaccines have only been available for 9 months without long term data. Each individual should be able make their own personal medical decision and risk-benefit analysis with the guidance of their provider without coercion, duress, or harassment.

4. Beyond the expensive monoclonal antibody infusions, there are multiple cheap, effective, oral medications which have been shown to be effective in mitigating the severity of COVID-19 infections which are NOT currently being prescribed or recommended by providers. If providers attempt any "off label" treatments they are censored, blacklisted or treated as pariahs. The lack of any other early treatment of disease is the largest contributor to the increase of hospitalizations being seen. At a separate meeting, many of us would be willing to spearhead implementation and rigorous study of these early therapeutics.

5. We are unclear about the endpoint of this endeavor. If we look at fully vaccinated cruise ships or countries with high vaccination rates such as Israel and Great Britain, we see that cases and death continue to breakthrough. Looking to populations further along mass-vaccination than Kentucky, we are seeing lowering effectiveness of the vaccine to the current Delta variant. We are being asked to forego our own medical reasoning, judgement, and conscience to promote this former vaccine strategy of decreasing efficacy.

6. We understand that you often look to the CDC for your recommendations and guidance. The CDC does not mandate vaccination for their employees nor have they recommended mandates. So, why has St. Elizabeth Healthcare decided to go beyond their recommendations on this matter?

7. You have trusted and respected our medical decision making as physicians and providers in the community to-date. We have been trained to look critically at scientific data and make medical decisions using evidence-based medicine. We urge you not to make decisions based on fear and wishful thinking. We urge you to recognize and defend the science and our medical expertise. Furthermore, we are open to and would welcome scientific, open-debate with other physicians with opposing conclusions.

8. The healthcare workers of the St. Elizabeth system have all labored as essential workers tirelessly throughout the pandemic. They took on personal risk and provided the best possible care despite no available vaccines. They have spent years training to do their jobs and sacrificed their health and time with family and friends to care for the sick. St. Elizabeth front-line workers gladly accept these sacrifices as they are consistent with their calling. We simply ask that you rescind this mandate, further study these vaccines, and allow personal body integrity for each St. Elizabeth employee. Please be "right here" for St. Elizabeth employees too.

Our goals are the same. We desire to see the health and flourishing of our entire community and the world at large. We look forward to further dialogue.

Sincerely,

St. Elizabeth Healthcare Physicians and Providers

Matthew Grunkemeyer, MD
Justin Klanke, MD
Amy DiChiara MD
Anthony Alvarez MD
Audrey Ertel MD
Brandon Kohrs, DO
Craig Sanders, DO
Charles Breen, MD
Harel "Rocky" Rachovistsky, MD
Howard Schertingzer, MD
Howard Stroupe, MD
Jonathon Spanyer, MD
Matt Grunkemeyer, MD
Rick Abrahamson, MD
Ron Aurer, MD
Ryan Moon, MD
Joey Warren MD
Suzana Brozovic, MD
William Beers, MD
Mike Greiwe, MD
Lisa Judge, MD
Adam Miller, MD
Gene Burchell, MD
Angie Marshall, CRNA
Brent Plummer, APRN

Marjorie Reeves, APRN
Ed Harris, APRN
Jason Gregg, APRN
Kevin Hickey, CRNA
Kim Bridges, CRNA
Kristin Sommer, CRNA
Michael LaVoy, CRNA
Monica Blackburn, CRNA
Teresa Geis, CNRA
Wendi Stroupe, CNRA
Christine Marchetta, CRNA
Jenna Ionna , APRN
Kelly Rawe, APRN
Nick Mai, APRN
Kristin Boudreaux, APRN
Anonymous SEP/H physicians
Anonymous midlevel providers

EXHIBIT 2

Monday, August 16, 2021.

Dear Mr. Garren Colvin, Dr. Robert Prichard, and the Board of St. Elizabeth Healthcare:

This letter is an appeal for you, representing St. Elizabeth Healthcare and St. Elizabeth Physicians, to reconsider the recent COVID-19 vaccine mandate imposed on all your employees to complete this new COVID-19 "vaccine" series by October 1, 2021. While there are many approaches one can discuss on this matter, I wanted to focus my appeal by grounding it in scientific, medical information.

This document is intended to be seen as a professional document, focused on my medical and scientific concerns as a physician. I believe I am doing my professional duty to inform the St. Elizabeth system of the current medical literature on this topic so that our system can be best served. This document is not to be construed to represent my personal, individual beliefs re: personal vaccination.

My appeal is for St. Elizabeth Healthcare/Physicians to:

(1) Base decision-making on the actual scientific, factual information (of which I intend to highlight here)—not presumptions, assumptions, hopes, nor bureaucratic declarations.

(2) Base decision making on reasoning and rationality—not fear and financial nor political pressure, nor just following the loudest voice(s),

(3) Uphold the Physician's Oath of, "First, Do No Harm."

(4) And ultimately, change the tide in your approach to this issue by being a Leader in our region (of which I have suggestions).

This document contains a lot of detail. This is a complex issue with a lot of confusing, mixed information out there. For this reason, I wanted to take the time to reference my statements so that you can see it is rooted in scientific information and not empty rhetoric and emotional appeals. It is my hope that you would take the time to check out these resources—even follow the links embedded in the document, so you can feel comfortable and confident in making the changes needed.

Quickly, I would like to define a couple terms, as there often appears to be a lot of confusion and interchange of these definitions:

- **SARS CoV-2** is the virus that causes the infection. (For ease, I may refer to this at times in this document as "the virus").
- **COVID-19** is the name of the clinical disease and manifestation of symptoms brought upon by the SARS-CoV-2 virus.
- **Vaccine** - these COVID-19 "vaccinations" are not vaccinations as we have ever defined vaccination before. Historically, a vaccination was inoculating the patient with the pathogen, live or attenuated, or a portion of the pathogen. Subsequently, the host's immune system mounts an immune response as it best sees fit. These COVID-19 injections are actually rebranded as a vaccine. Sure, it induces an immune response, but instead of the pathogen being injected, a protein genetic code is injected in the form of

mRNA via a viral vector, forcing the body to create a foreign protein representing a small component of the pathogen's proteome. Subsequently, the host's immune system is allowed to respond. This falls under the definition of "gene therapy," as defined by the FDA[1]. While, these COVID-19 "vaccinations" are really gene-therapy, for the sake of this document, I will refer to it as a "vaccine" so as not to be too contentious throughout this discussion. But, I simply want to call to attention that although I will use this term, "vaccine," these inoculations are markedly different from any other human vaccination to-date and best fits under the classification of "gene therapy."

MIT Study: Individuals with vaccine Hesitancy (re: COVID-19 vaccinations) are "Highly Informed, Scientifically Literate," and "Sophisticated. They are critical about the data sources, and are not "anti-Science."[2]

Before starting, I do want to acknowledge that we are seeing overall clinical benefit in vaccination in that the large majority of patients being hospitalized at this time are unvaccinated patients. And although there are still some breakthrough cases of vaccinated patients being hospitalized, the overall number is low and lower than the unvaccinated. We can be in agreement on this.

OUTLINE:

Here is the quick outline of what I would like to cover. I then go further into more detail providing support and explanation for these statements.

I. Elaboration of My Scientific Concerns:

(1) This vaccine does not do what St. Elizabeth Healthcare/Physicians thinks or claims it does. It does NOT prevent the transmission of SARS-CoV-2 virus. This is especially true with the Delta variant.

(2) Natural immunity is equal, if not superior to vaccination. Not allowing any concessions for previous immunity is not scientifically sound.

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[1] "Human gene therapy seeks to modify or manipulate the expression of a gene or to alter the biological properties of living cells for therapeutic use. Gene therapy is a technique that modifies a person's genes to treat or cure disease. Gene therapies can work by several mechanisms:

- Replacing a disease-causing gene with a healthy copy of the gene
- Inactivating a disease-causing gene that is not functioning properly
- Introducing a new or modified gene into the body to help treat a disease
- . . . There are a variety of types of gene therapy products, including: . . . **Viral vectors:** Viruses have a natural ability to deliver genetic material into cells, and therefore some gene therapy products are derived from viruses. Once viruses have been modified to remove their ability to cause infectious disease, these modified viruses can be used as vectors (vehicles) to carry therapeutic genes into human cells."

-From: https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products/what-gene-therapy (From 07/25/2018; Accessed July 13,2021).

[2] http://vis.csail.mit.edu/covid-story/ The Data Visualizations Behind COVID-19 Skepticism
Research By Crystal Lee, Tanya Yang, Gabrielle Inchoco, Graham M. Jones, and Arvind Satyanarayan
Interactive Article By Crystal Lee, Jonathan Zong, Anna Arpaci-Dusseau, Katherine Huang, Mateo Monterde, Ethan Nevidomsky, Tanya Yang, Anna Meurer, Soomin Chun, and Arvind Satyanarayan
March 1, 2021

(3) There are many Safety Concerns regarding the current vaccinations:

(i) mRNA encodes for the Spike protein of the virus, this is, unfortunately, the part of the virus that causes the pathogenic effect in its host.

(ii) mRNA and spike protein injected does not stay at or near the injection site and nearby lymphatics like has been thought to be the case of other vaccines. Accumulates in ovaries, crosses blood-brain barrier.

(iii) There may be some homogeny of the Spike protein to native human tissue (ie: placental tissue), and antibodies created could potentially be a simultaneous target to placental tissue. This is an unknown—it has not been adequately studied. However, there are several legitimate scientists that have put out a call to action to investigate this. We do not know what we do not know.

(iv) Numbers reported to VAERS are astonishing. The numbers reported far surpass the adverse reactions reported for any other vaccine to-date. The CDC admits they do not have the personnel nor updated technology to adequately follow-up and investigate these reports.

(v) Numerous anecdotal reports of significant and severe adverse events. In the absence of robust, systematic, open and transparent reaction monitoring, all we have is anecdotal reports.

- Just within this system: Physician with lower extremity paralysis started about 4 hours after her second Moderna vaccine. This resolved about 12 hours later. Went to the ER for steroid shot. Long-term sequela, new asthma in this very active, very fit individual.
- Similar reports in 1 NP with left sided paralysis that lasted about 12 hours. Did not go to the ER; did not seek medical care.
- Another NP with lower extremity paralysis. This also resolved in 12 hours.
- Numerous dermatologic issues.

(vi) Mechanism of action of adverse events is postulated to be related to Spike-protein's systemic and inflammatory effects and microthrombosis as is seen in COVID-19 disease combined with the distribution of the spike protein and/or antibodies generated throughout the body.

(4) Widespread vaccination using a non-sterilizing vaccine (vs. targeted population to most vulnerable) during a widespread Pandemic may be contributing to the development of variants.

(5) There are promising options for inexpensive, easily accessible treatment that can, and should, be initiated in the outpatient.

(6) No long-term (ie: 1-3 years) information on safety outcomes.

II. Additional Questions

III. Suggestions on How to Address Policy Change

Elaboration*:

Note: I quote many studies here of which I have all reviewed. There is a lot of information in each of these studies. Each individual study may illustrate multiple points, and the authors may draw specific conclusions—some of which are supported in their study, others also may be their own opinion and conjecture of potential implications. This document is not exhaustive, and I do not cite all the "points" made in each article. I try to stay focused on the particular element being discussed. I try to be balanced and state some limitations that are applicable to the relevant issue at hand. I simply want to state that I acknowledge there are other points made in these papers being referenced; I am just unable to mention everything and try to stay focused on point I am trying to support.

(1) **This vaccine does not do what St. Elizabeth Healthcare/Physicians thinks or claims it does. It does NOT stop the transmission of the SARS-CoV-2 virus. This is especially true with the Delta variant.**

St. Elizabeth Healthcare/Physician's letter states: "vaccines will provide strong protection against unintentionally carrying the virus to work and spreading it to patients and peers."

- What is the data for this statement?
- In my research, medical, and scientific understanding, the opposite of this is true.
- **This next point is the BIGGEST, scientific misinformation that has been misleading and propagated among media, government officials, and is very IMPORTANT to clarify.**
- **Current COVID-19 vaccines are non-sterilizing.[3]** Meaning, these vaccines do not PREVENT infection and transmission of the SARS-CoV-2 virus. It was not designed nor studied to evaluate this. The vaccines were designed to decrease severity of the clinical disease of COVID-19, but it does not prevent infection.
    - Ideal immune response is "sterilizing" = it completely protects against a new infection and does not allow the virus to enter the cell and replicate at all and, therefore, prevent viral shedding.[4] (Examples of sterilizing vaccines: MMR, Varicella, OPV in immune competent individual).
    - "Non-sterilizing" vaccines – permit the virus to infect cells, therefore viral replication and shedding can occur, and infection can spread to others. Acts more as prophylactic therapy that acts to reduce or eliminate symptomatic disease. (Ex: all COVID-19 vaccinations, influenza vaccination, injected polio).
        - Don't know you are sick, virus is replicating and shedding, more likely to unknowingly spread the infection to others.
    - COVID-19 vaccines create IgG specific immunity in the serum, but it does not create IgA antibodies needed at the mucosal surface to prevent infection.[4]
    - This point is not a surprise to vaccine developers. If you look closely at the vaccine study, they intentionally did NOT test any recipients of the vaccine for asymptomatic infection. They only tested patients who developed a significant illness. This is also the same reason why the CDC decided May 2021 to stop testing vaccinated patients in the community for infection because viral infection is actually quite common in vaccinated individual.[5]
    - Media and Pharma has capitalized on the common-person's misunderstanding and easy confusion of the terms "SARS CoV-2 virus" and "COVD-19" which has become

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[3] Denninger , Karl. Covid Vaccines are Non-Sterilizing. https://wentworthreport.com/2021/08/06/covid-vaccines-are-non-sterilizing/

[4] Jacobs, John. Non-sterilising mucosal immunity, Jan 4, 2021. https://hartblik.weebly.com/non-sterileimmune.html

[5] https://www.newsweek.com/why-did-cdc-stop-counting-mild-asymptomatic-breakthrough-covid-cases-1616802

interchangeable words in day-to-day conversation, but actually have different meanings. So "95% effective at preventing COVID-19"—most people understood this to mean preventing infection, which is false. Vaccines were found to prevent symptomatic illness, not infection.

- This misunderstanding is one big reason non-medical individuals, celebrities, personalities are very upset that they are told to mask back up despite being vaccinated. They thought vaccination would keep them from spreading the virus, thus prevent the need for wearing a mask.

- Again, there is a difference between "sterilizing immunity" (prevents a pathogen establishing infection: invading host's cells and replicating) vs "effective immunity" (prevent illness but still lead to asymptomatic infection).
  - Influenza vaccination is an example of effective immunity.[6]

- This is not new information. Per November 2020 Medscape interview[7]:

  "Scientists involved in oversight of the Operation Warp Speed COVID-19 vaccine trials are tempering excitement about efficacy, noting that the studies haven't shown yet whether the products can prevent transmission of the SARS-CoV-2 virus. . . .

  'We don't know if people can become infected and thus also transmit even with vaccination,' said former US Food and Drug Administration Commissioner Margaret Hamburg, MD, in a November 18 briefing on COVID-19 vaccines sponsored by the American Public Health Association (APHA) and the National Academy of Medicine (NAM).

  For that reason and others — including if there isn't significant uptake of vaccine — 'people can expect to still be wearing masks, still be asked to follow non-pharmaceutical public health measures that we've all come to know so well,' she said.

  'It may take a year or more to get the studies to answer the transmission question, said Larry Corey, MD, who helps oversee the vaccine trials as part of the National Institutes of Health's (NIH's) COVID-19 Prevention Network.'[7]

- August 6th, 2021, CDC director Rochelle Walensky publicly announced that COVID vaccines do NOT prevent transmission and that someone vaccinated can unknowingly

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[6] Choi A, Ibañez LI, Strohmeier S, Krammer F, García-Sastre A and Schotsaert M (2020) Non-sterilizing, Infection-Permissive Vaccination With Inactivated Influenza Virus Vaccine Reshapes Subsequent Virus Infection-Induced Protective Heterosubtypic Immunity From Cellular to Humoral Cross-Reactive Immune Responses. Front. Immunol. 11:1166. doi: 10.3389/fimmu.2020.01166

- "In the absence of neutralizing antibodies, there are other mechanisms that contribute to protection against influenza-related disease. Cytotoxic T lymphocytes, non-neutralizing antibodies, and innate immune responses . . . [a]lthough protective from disease, these immune responses are often infection-permissive. Because they do not fully neutralize the virus, viral replication still occurs and virus-host interactions can be initiated." Experimentation demonstrates single-dose influenza vaccine to mice prevented significant disease, inflammation, and pathologic tissue damage while still detecting virus in the lungs. And, the virus detected was the result of replication, not the initial inoculum. Thus, infection-permissive.

[7] Ault, Alicia. Can a COVID-19 Vaccine Stop the Spread? Good Question. November 20, 2020. [https://www.medscape.com/viewarticle/941388] Accessed August 17,2021.

pass on asymptomatic infection to someone else (and is the reason for universal masking recommendations).[8]

- **Dr. Rochelle Walensky:** Our vaccines are working exceptionally well. They continue to work well for Delta in regard to severe illness and death being prevented. **But what they can't do anymore is prevent transmission.** So, if you are going home to somebody who has not been vaccinated [or is immunosuppressed, frail, or with comorbidities], I would suggest you [who are vaccinated] wear a mask in public indoor settings.
- **Wolf Blitzer (CNN):** Especially if there is a breakthrough case, you get COVID, you are fully vaccinated, but you are totally asymptomatic, you can still pass on the virus to someone else, is that right?
- **Dr. Rochelle Walensky:** That's exactly right, and that's where our masking recommendation came from.
- **Wolf Blitzer (CNN):** So important, these masks.

- Recent data from England shows vaccine effectiveness in preventing infection is decreased with Delta variant[9]:
  - Stratified community population in England (100-150K) followed monthly with self-administered RT-PCR testing and survey questionnaire (REACT-1 study) to assess virus prevalence.[10]
  - Observed an exponential growth of SARS-CoV-2 infection between May 20 to July 12, 2021 despite having one of the highest adult vaccination rates internationally with a doubling time of about 17 days. From these 2 time periods, Delta variant prevalence went from 78.3% (rest were Alpha) to 100% Delta for 6/24 to 7/12/2021 time period.[11]
  - Of the + swabs for infection, **44% of the infections were in the vaccinated group**! This is nearly half!
  - This study calculated vaccine effectiveness in preventing infection to be only 49% during the time of 100% Delta prevalence. [*Note: can't necessarily say the vaccine "prevented infection" as do not have data of exposure risks, and testing was only monthly.*]

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[8] https://www.realclearpolitics.com/video/2021/08/06/cdc_director_vaccines_no_longer_prevent_you_from_spreading_covid.html#!

[9] Elliot P, Haw D, Wang H, et al. REACT-1 round 13 final report: exponential growth, high prevalence of SARS-CoV-2 and vaccine effectiveness associated with delta variant in England during May to July 2021. 4 August 2021. [Preprint] www.imperial.ac.uk/medicine/research-and-impact/groups/react-study/real-time-assessment-of-community-transmission-findings.

- Prevalence of infection in vaccinated went from 0.07% to 0.40% compared to 0.24% to 1.21% in unvaccinated. The ratio of infections between vaccinated and unvaccinated remained the same.

[10] Riley S, Atchison C, Ashby D *et al.* REal-time Assessment of Community Transmission (REACT) of SARS-CoV-2 virus: Study protocol [version 2; peer review: 2 approved]. *Wellcome Open Res* 2021, **5**:200 (https://doi.org/10.12688/wellcomeopenres.16228.2)

[11] Elliot P, Haw D, Wang H, et al. REACT-1 round 13 final report: exponential growth, high prevalence of SARS-CoV-2 and vaccine effectiveness associated with delta variant in England during May to July 2021. 4 August 2021. [Preprint] www.imperial.ac.uk/medicine/research-and-impact/groups/react-study/real-time-assessment-of-community-transmission-findings.

- Prevalence of infection in vaccinated went from 0.07% to 0.40% compared to 0.24% to 1.21% in unvaccinated. The ratio of infections between vaccinated and unvaccinated remained the same.

  - There was 59% vaccine effectiveness against symptomatic infection of COVID-19 (fever, loss or change of sense of smell or taste, new persistent cough).
  - Therefore, **41%** of these positive infections **in vaccinated patients** were **asymptomatic**.
- Barnstable County, Massachusetts SARS-CoV-2 outbreak in July 2021 after multiple large indoor and outdoor events; 469 new cases.[12]
  - 74% of COVID-19 cases were in fully vaccinated individuals.
  - Of those sequenced, 90% from Delta variant.
  - 4 of the 5 hospitalized were those vaccinated. No deaths.
  - RT-PCR swabs of 127 vaccine breakthrough cases had similar cycle threshold (Ct) values to 84 unvaccinated (median= 22.77 and 21.54, respectively). This suggests similar viral load in nasopharynx and similar ability to transmit infection.
- Wisconsin study found NO difference in viral load (Ct) among vaccinated vs unvaccinated individuals getting testing done at 1 lab between 6/28 to 7/31/21. Study limitation is clinical status of individuals, reason and timing of testing, and self-selection bias.[13]
  - 39% of positives among fully vaccinated in Dane County, WI. Small sampling—88% Delta.
  - Including other counties, 27.1% positives in fully vaccinated. However, 83% viral loads with Ct<30; 33% vaccinated with viral loads Ct<20 suggesting very high viral loads.
  - Virus infectivity was correlated to cytopathic effects in viral culture after 5 days of replication (Figure 2)[14].
  - "These data suggest that a substantial proportion of individuals with SARS-CoV-2 vaccine breakthrough infections during our study period have levels of SARS-CoV-2 RNA in nasal secretions that are consistent with the ability to transmit the virus to others."
  - "Policies that create a dichotomy between vaccination and routine testing should be re-evaluated."

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[12] Brown CM, Vostok J, Johnson H, et al. Outbreak of SARS-CoV-2 Infections, Including COVID-19 Vaccine Breakthrough Infections, Associated with Large Public Gatherings — Barnstable County, Massachusetts, July 2021. MMWR Morb Mortal Wkly Rep 2021;70:1059-1062. DOI: http://dx.doi.org/10.15585/mmwr.mm7031e2external icon.

- Among the 469 cases in Massachusetts residents, 346 (74%) occurred in persons who were fully vaccinated; of these, 301 (87%) were male, with a median age of 42 years. Vaccine products received by persons experiencing breakthrough infections were Pfizer-BioNTech (159; 46%), Moderna (131; 38%), and Janssen (56; 16%); among fully vaccinated persons in the Massachusetts general population, 56% had received Pfizer- BioNTech, 38% had received Moderna, and 7% had received Janssen vaccine products.
- Massachusetts residents had 69% vaccination coverage among those eligible.

[13] Kasen K. Riemersma, Brittany E. Grogan, Amanda Kita-Yarbro, Peter Halfmann, Anna Kocharian, Kelsey R. Florek, Ryan Westergaard, Allen Bateman, Gunnar E. Jeppson, Yoshihiro Kawaoka, View ORCID ProfileDavid H. O'Connor, View ORCID ProfileThomas C. Friedrich, Katarina M. Grande. Shedding of Infectious SARS-CoV-2 Despite Vaccination when the Delta Variant is Prevalent - Wisconsin, July 2021. Version 3, August 11, 2021. https://doi.org/10.1101/2021.07.31.21261387

[14] Kasen K. Riemersma, Brittany E. Grogan, Amanda Kita-Yarbro, Gunnar E. Jeppson, David H. O'Connor, View ORCID ProfileThomas C. Friedrich, Katarina M. Grande. Vaccinated and unvaccinated individuals have similar viral loads in communities with a high prevalence of the SARS-CoV-2 delta variant. Version 2, July 31, 2021. https://doi.org/10.1101/2021.07.31.21261387

- Vaccinated individuals with breakthrough cases by Delta variants had a high viral load (low Ct), not significantly different than unvaccinated patients with COVID-19 from Delta in Houston, TX.[15]
    - Supports finding that fully vaccinated can transmit SARS-CoV-2 to others (given high viral load in nasopharynx).
    - Admittedly, doesn't assess for viral clearance day-to-day.
- There is 3-fold reduced sensitivity of antibody neutralization to SARS-CoV-2 B.1.617.2 (Delta variant) in vaccinated individuals compared to Alpha variant (and 16-fold reduction for Beta). The Delta variant contains diverse mutations in the N-terminal domain (NTD) and the receptor-binding domain (RBD) of the SARS-CoV-2 spike protein. This study suggests the spread of the Delta variant is associated with escape from antibodies that target non-RBD and RBD epitopes of the spike protein.[16]
- Some PCR studies[17] do suggest that vaccinated individuals will clear the virus and decrease the shedding earlier than unvaccinated individual, but VIRAL SHEDDING is STILL HAPPENING in the vaccinated individual. (Side note—this study is unable to differentiate from live, infectious virus vs infectious virus.)
    - Viral loads in Delta variant SARS-CoV-2 (RT-PCR Ct) similar between vaccinated ("breakthrough") and unvaccinated groups at diagnosis, but viral loads did decrease faster in unvaccinated individuals as measured by RT-PCR Ct.[17]
- Cevik et al.[18] meta-analysis on viral dynamics and RNA shedding of vial virus in SARS-CoV, SARS-CoV-2, and MERS. SARS-CoV-2 viral load peaked within 1st week after symptom onset (sooner than other 2) with highest risk of transmission very early in disease course (a few days before & within 5 days of symptom onset).
    - Although SARS-CoV-2 may have prolonged RNA shedding up to 83 days in upper respiratory tract, no live virus was isolated from culture beyond day 9 despite persistently high viral RNA loads.
    - Viral loads similar b/w asymptomatic and symptomatic individuals with SARS-CoV-2, but faster viral clearance among asymptomatic.

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[15] James M. Musser, Paul A. Christensen, Randall J. Olsen, S. Wesley Long, Sishir Subedi, James J. Davis, Parsa Hodjat, Debbie R. Walley, Jacob C. Kinskey, Jimmy Gollihar. Delta variants of SARS-CoV-2 cause significantly increased vaccine breakthrough COVID-19 cases in Houston, Texas. medRxiv 2021.07.19.21260808; doi: https://doi.org/10.1101/2021.07.19.21260808

- Sampled 85% of 5,756 COVID-19 cases b/w 3-15-21 to 7-24-21. 22.7% Delta variant. Eventually, Delta became supermajority (93.7%) of cases.
- 8.4% (414/4920) considered vaccine breakthrough cases. This does mean 88.6% of cases were unvaccinated. Vaccinated patients with COVID-19 did have less hospitalization compared to unvaccinated (all variants): (35.5% vs 52.9%).
- Breakthroughs: Pfizer: 85%, Moderna: 11%, J&J: 2%.
- Higher vaccine breakthrough for Delta: 17.4% vs 5.8%.
- Delta variant vs other variants had less ventilation requirement (5.9% vs 8.1%), less death (1.3% vs 4.0%), less hospitalization (40.9% vs 54.6%)

[16] Planas, D., Veyer, D., Baidaliuk, A. *et al.* Reduced sensitivity of SARS-CoV-2 variant Delta to antibody neutralization. *Nature* **596,** 276–280 (2021). https://doi.org/10.1038/s41586-021-03777-9

[17] Po Ying Chia, Sean Wei Xiang Ong, Calvin J Chiew, Li Wei Ang, et al. Virological and serological kinetics of SARS-CoV-2 Delta variant vaccine-breakthrough infections: a multi-center cohort study. medRxiv 2021.07.28.21261295; doi: https://doi.org/10.1101/2021.07.28.21261295

[18] Muge Cevik, Matthew Tate, Ollie Lloyd, Alberto Enrico Maraolo, Jenna Schafers, Antonia Ho. SARS-CoV-2, SARS-CoV, and MERS-CoV viral load dynamics, duration of viral shedding, and infectiousness: a systematic review and meta-analysis. Lancet Microbe 2021; 2: e13–22. https://doi.org/10.1016/S2666-5247(20)30172-5

The above scientific data as well as statements from the CDC directly contradicts the statement St. Elizabeth Healthcare/Physicians has made that "vaccines will provide strong protection against unintentionally carrying the virus to work and spreading it to patients and peers." Perhaps the individuals making this policy with St. Elizabeth Healthcare were unaware of this information and data when making this policy. Admittedly, it has only been in the last 2 weeks that this information has been made more public and more widely known, and likely after this policy decision was made by St. Elizabeth Healthcare/Physicians. (Ex: Email went out to associates 8/5/21 at 7:12am and Dr. Walensky's statement came out 8/6/21.)

We can agree that to-date, on a population-basis, it appears that vaccination has been effective in preventing COVID-19 hospitalization in that a vast majority of patients in this region who are hospitalized are those who are unvaccinated. The proper way to interpret this information and the information I presented above is that to-date, current COVID-19 vaccinations are an effective therapeutic for the individual. Based on the information presented above, we cannot say that vaccination PREVENTS spreading infection to our patients/colleagues/neighbors (*perhaps vaccination may *decrease* viral shedding in comparison to the unvaccinated, the difference appears to be a difference of 2-4 days, and the unvaccinated would be more likely to have symptoms by that point and be able to be quarantined while the vaccinated may remain asymptomatic and find no reason to quarantine, making the potential practical difference in rate of viral shedding b/w the vaccinated and unvaccinated individual to the public be nil*). We **can** say that vaccination protects the individual from significant disease from COVID-19, even though imperfect with the Delta variant.

Since the current COVID-19 vaccinations are effective for the individual, but not preventative in a population-transmissibility basis, I do not see a legitimate scientific reason for St. Elizabeth Healthcare/Physicians to mandate vaccination for all employees, staff, and volunteers. To date, SEH/SEP has not mandated any therapeutics that benefit the individual. Ie: we don't require proof of daily insulin compliance in the diabetic to prevent hospitalization for DKA or other diabetes-related complications. We don't mandate compliance with antihypertensives, statins, nor daily aspirin to prevent hospitalizations and death from cardiovascular disease, heart attacks, nor strokes. We encourage good health practices and would encourage following the recommendations of their treating physicians, but we don't mandate on the individual level. Ultimately, in a free country, the individual has to decide if they are going to comply with the sound medical advice they have been given or not. If the current COVID-19 vaccinations were actually sterilizing, actually preventing of viral cell invasion of the host, and thus truly preventative of infection and spread, then it would make more sense for potential mandate in the healthcare setting. But since the current COVID-19 vaccinations are infection-permissive, mandating vaccination (and the reasons cited for doing so) is not consistent with sound scientific information. **Therefore, it is on this main point, that I urge St. Elizabeth Healthcare/Physicians to reconsider their COVID-19 vaccine mandate policy.**

If the above is not enough for you to reconsider your policy, then I have the following points in decreasing importance/relevance:

(2) Natural immunity is equal, if not superior to vaccination. Not allowing any concessions for previous immunity is not scientifically sound.

- First off, vaccine development has always been modelled after natural immunity. Vaccine creators study natural immunity to the greatest detail and try to artificially recreate a similar response but without significant symptomatic or pathologic disease.
- Prior exposure to SARS-CoV-2 creates a broad immune response generated towards SARS-CoV-2 targeting different epitopes within separate proteins in the viral proteome, irrespective of severity of infection (ie: asymptomatic, mildly symptomatic, or hospitalized)[19].
- Vaccine-antibody resistance observed for variants B.1.1.7 (alpha) and B.1.351 (beta)[20]:
    - These variants and other reported variants of concern have "extensive mutations in the spike protein."
- Those with previous mild to moderate COVID-19 infection found to have effective antibodies against the emerging variants of concern (VOC), including: B.1.1.7 (Alpha), B.1.351 (Beta), B.1.427, B.1.429, B.1.526, P.1 (Gamma), P.2, B.1.617.1, and B.1.617.2 (Delta)[21]:
    - "Our study demonstrates that convalescent subjects previously infected with ancestral variant SARS-CoV-2 produce antibodies that cross-neutralize emerging VOCs with high potency. Structural and functional analyses reveal that antibody breadth is mediated by targeting a site of vulnerability at the RBD tip offset from major mutational hotspots in VOCs.
- Expect T-cell cellular immunity with previous infection to be long-lasting. T-cell immunity to SARS-CoV-1 known to persists for up to 6 to 11 years.[22][23]
- From a review on SARS-CoV-2 Immune responses and Immunity[24]:
    - "The vast majority of SARS-CoV-2–infected individuals seroconvert following SARS-CoV-2 infection. Reviews of the published literature indicate that >90% patients develop IgG seropositivity and neutralizing antibodies following primary infection, ranging between 91 and 99% in large studies. A scoping review performed by the Irish Health Information and Quality Authority (HIQA), to evaluate the long-term duration of immune responses following SARS-CoV-2

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[19] **Immunity to SARS-CoV-2 Independent of Severity of SARS-CoV-2 COVID-19 Infection.**
June 4, 2021. S.S. Nielsen et al. / EBioMedicine 68 (2021) 103410

[20] Wang P, Nair MS, Liu L, Iketani S, Luo Y, Guo Y, Wang M, Yu J, Zhang B, Kwong PD, Graham BS, Mascola JR, Chang JY, Yin MT, Sobieszczyk M, Kyratsous CA, Shapiro L, Sheng Z, Huang Y, Ho DD. Antibody resistance of SARS-CoV-2 variants B.1.351 and B.1.1.7. Nature. 2021 May;593(7857):130-135. doi: 10.1038/s41586-021-03398-2.

[21] Wang L, Zhou T, Zhang Y, Yang ES, Schramm CA, Shi W, et al. Ultrapotent antibodies against diverse and highly transmissible SARS-CoV-2 variants. Science. 2021 Aug 13:373(6556):eabh1766. doi: 10.1126/science.abh1766. Epub 2021 Jul 1. PMID: 34210892.

[22] Yang L-T, Peng H, Zhu Z-L, et al. Long-lived effector/central memory T-cell responses to severe acute respiratory syndrome coronavirus (SARS-CoV) S antigen in recovered SARS patients. Clinical immunology (Orlando, Fla) 2006;120 (2):171–8.

[23] Fang Tang, Yan Quan, Zhong-Tao Xin, Jens Wrammert, Mai-Juan Ma, Hui Lv, Tian-Bao Wang, Hong Yang, Jan H. Richardus, Wei Liu and Wu-Chun Cao. Lack of Peripheral Memory B Cell Responses in Recovered Patients with Severe Acute Respiratory Syndrome: A Six-Year Follow-Up Study. J Immunol June 15, 2011, 186 (12) 7264-7268

- While no B cell antibody response was seen, 61% of SARS-recovered patients had memory T-cell response 6 years from infection.

[24] "Immune responses and immunity to SARS-CoV-2," European Centre for Disease Prevention and Control. https://www.ecdc.europa.eu/en/covid-19/latest-evidence/immune-responses

infection, identified five studies that investigated immune responses at ≥6 months post-infection, including two studies at ≥8 months post-infection.[25] In general, studies reported a waning of antibody responses in the late convalescent period (3–6 months post-infection). However, T-cell and memory B-cell responses were still present, and in many cases increased, up to eight months post-infection in all study participants.

- SARS-CoV-specific CD8 T cell responses targeting the SARS-CoV membrane (M) and nucleocapsid (N) found in convalescents at 9 and 11 years post-infection[26].
- Note: Both humoral immunity and cell-mediated immunity (CD8 T-cells especially) have important roles for vaccine-induced immunity for intracellular infections such as viruses. This discussion reviewed by Hellerstein[27]:
    - T-cell responses have been better markers than antibody response after natural coronavirus infection.[26, 27]
    - Yellow Fever and Smallpox vaccines illustrate this well. They both generate effective and long-lived immune protection and both the following features of cellular immunity: "CD8 T-cells with broad specificity, high magnitude, polyfunctionality, high proliferative potential and long-term persistence."
- Grifoni et al. review of 25 different studies from 1,197 human subjects (870 COVID-19 and 327 unexposed controls) and report on the wide breath of T-cell epitope targets identified from natural SARS-CoV-2 infection.[28]
- "A total of 1,434 unique, non- redundant CD4 and CD8 epitopes have been defined, with the top 10 antigens accounting for 86% of the total. In these 10 most dominant antigens, a median of 87 epitopes (range of 33 to 396) is recognized. The data presented above demonstrates that T cell responses are multi-antigenic, with structural antigens being broadly recognized, but with other proteins such as nsp3, nsp12, ORF3a, and ORF8 also being vigorously recognized. Furthermore, data from Tarke et al.[29] show that each individual is conservatively estimated to recognize, on average, 19 different CD4 and 17 different CD8 epitopes."
- Overall, the data accumulated as of March 15, 2021, reveals that over 1,400 different SARS-CoV-2-derived peptide sequences are reported as being recognized by human T cell responses, and which consist of 382 CD4 and 1,052 CD8 epitopes based on the meta-analysis performed in this review.

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[25] Health Information and Quality Authority (HIQA). Duration of immunity (protection from reinfection) following SARSCoV-2 infection - 8 March 2021. Dublin: HIQA; 2021. Available at: https://www.hiqa.ie/sites/default/files/2021-03/Duration-of-protective-immunity_Evidence-Summary.pdf

[26] Wing Ng, Adeline Chia, Anthony T. Tan, Ramesh S. Jadi, Hoe Nam Leong, Antonio Bertoletti, Yee-Joo Tan, Memory T cell responses targeting the SARS coronavirus persist up to 11 years post-infection, Vaccine, Volume 34, Issue 17, 2016, Pages 2008-2014, ISSN 0264-410X, https://doi.org/10.1016/j.vaccine.2016.02.063.

[27] Hellerstein M. What are the roles of antibodies versus a durable, high quality T-cell response in protective immunity against SARS-CoV-2? Vaccine X. 2020 Dec 11;6:100076. doi: 10.1016/j.jvacx.2020.100076. Epub 2020 Aug 28. PMID: 32875286; PMCID: PMC7452821.

[28] Grifoni A, Sidney J, Vita R, Peters B, et al., SARS-CoV-2 human T cell epitopes: Adaptive immune response against COVID-19. Cell Host & Microbe 29, July 14, 2021. (Review) https://doi.org/10.1016/j.chom.2021.05.010

[29] Tarke A, Sidney J, Kidd C.K, et al., Comprehensive analysis of T cell immunodominance and immunoprevalence of SARS-CoV-2 epitopes in COVID-19 cases. Cell Rep Med. 2021; 2: 100204. DOI: https://doi.org/10.1016/j.xcrm.2021.100204

- "The broader the T cell response, in terms of epitopes, the less likely viral escape becomes, because any individual epitope that can escape through viral mutation would represent a small fraction of the overall immunity and thus represent a small selective pressure. Given that SARS-CoV-2 is a large RNA virus, the breadth of the CD4 and CD8 T cell responses is not surprising, per se."[30]
- Indeed, it appears that SARS-CoV-2 T-cell immunity is not affected by mutations in the variants analyzed (B.1.1.7, B.1.351, P.1, and CAL.20C) by Tarke et al. for convalescent subjects and vaccinees of Moderna and Pfizer in the vast majority of CD4+ and CD8+ T cell epitopes.[31]
    - 93% and 97% of CD4+ and CD8+ are 100% conserved over these variants.

Clinical, real-world evidence, also supports that natural immunity from prior infection is indeed protective of future infection:

- Cohen et al.[32] prospectively followed 254 COVID-19 recovered patients from Seattle and Atlanta longitudinally for eight months (starting 4/2020) and found them to have durable, broad-based immune responses.
    - SARS-CoV-2 spike binding and neutralizing antibodies had a biphasic decay with an extended half life of >200 days and plateau suggesting the generation of longer-lived plasma cells.
    - Spike-specific IgG memory B cells persist (good for rapid antibody response upon reexposure).
    - Virus-specific CD4+ and CD8+ T cells are polyfunctional.
        - CD4+ T cells equally target several SARS-CoV-2 proteins
        - CD8+ T cells preferentially target the nucleoprotein (should consider this as a target for future vaccines).
- Prospective cohort study Vitale et al.[33] supports previous infection protective against reinfection. They looked at consecutive patients with testing b/w Feb to July 2020 in Lombard, Italy.:
    - Cohort of 1,579 patients with + RT-PCR (Ct<35) both symptomatic & asymptomatic followed
        - 280 day avg follow-up, only 5 reinfections (defined >90 d from initial infection): 0.31%. Only 1 hospitalized.
    - Cohort of 13,496 initially negative RT-PCR followed
        - 528 subsequently + primary infection: 3.9%
    - Incidence density per 100,000 person-days was **1.0 for reinfection vs 15.1 for new infections.**
        - The difference is remarkable.

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[30] Grifoni A, Sidney J, Vita R, Peters B, et al., SARS-CoV-2 human T cell epitopes: Adaptive immune response against COVID-19. Cell Host & Microbe 29, July 14, 2021. (Review) https://doi.org/10.1016/j.chom.2021.05.010

[31] Tarke et al., 2021, Cell Reports Medicine 2, 100355 July 20, 2021. https://doi.org/10.1016/j.xcrm.2021.100355

[32] Cohen KW, Linderman SL, Moodie Z, et al. Longitudinal analysis shows durable and broad immune memory after SARS-CoV-2 infection with persisting antibody responses and memory B and T cells. *Cell Rep Med.* 2021;2(7):100354. doi:10.1016/j.xcrm.2021.100354

[33] Vitale J, Mumoli N, Clerici P, et al. Assessment of SARS-CoV-2 Reinfection 1 Year After Primary Infection in a Population in Lombardy, Italy. *JAMA Intern Med.* Published online May 28, 2021. doi:10.1001/jamainternmed.2021.2959

        - Do not know how this data will apply to emerging variants of concern, however.
- Large, multicenter, prospective cohort study of healthcare workers studied in England enrolled from June 18, 2020 to Dec 31, 2020 and followed to Jan 11, 2021, SIREN study, suggests previous infection of SARS-CoV-2 provided effective immunity to re-infection [34]:
    - Positive cohort with + RT-PCR: 8,278 participants developed 155 infections by RT-PCR (>90 days from initial infection,)
        - Note: do not have Ct data on positive cohort to see if lower Ct as >30 can be a false positive.
    - Negative cohort: 17,383 developed 1704 new + RT-PCR infections.
    - The incidence density was 7.6 reinfections per 100,000 person-days in the positive cohort, compared with 57.3 primary infections per 100,000 person-days in the negative cohort.
    - Report previous SARS-CoV-2 infection provided a 84% risk reduction for reinfection (adjusted incidence rate ratio [aIRR] 0·159, (95% CI 0.13–0.19) and 93% risk reduction for those with symptomatic infections (aIRR 0.074, 0.06–0·10).
        - This could be an underestimation b/c 49% of the episodes of reinfection were asymptomatic. Ct mean 28.0, range 13-45. We now know that Ct>30 can be unreliable and low correlation to infectious virus and may be a contaminant.
    - The median interval between primary infection and reinfection was more than 200 days.

St. Elizabeth Healthcare/Physician's letter states: "These vaccines have been proven safe and effective at **providing long-lasting protection against COVID**" -- This is not supported in recent data, especially with the Delta variant:

Natural immunity more robust immunity than COVID.[35]

- Data from Israel supports:[36] of 7,000 new cases 5/2021 outbreak, >3,000 of these cases in vaccinated (Pfizer) patients: 40% vs 72 cases in those with previous infection (<1%).
    - Vaccinated Israelis >6.72 times more likely to get infected after vaccination than after natural infection:

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[34] Hall VJ, Foulkes S, Charlett A, et al. SARS-CoV-2 infection rates of antibody-positive compared with antibody-negative health-care workers in England: large, multicentre, prospective cohort study (SIREN). *Lancet.* 2021; (published online April 9.) https://doi.org/10.1016/S0140-6736(21)00675-9

[35] Tarke A, Sidney J, Methot N, Zhang Y, Dan JM, Goodwin B, Rubiro P, Sutherland A, da Silva Antunes R, Frazier A, Rawlings SA, Smith DM, Peters B, Scheuermann RH, Weiskopf D, Crotty S, Grifoni A, Sette A. Impact of SARS-CoV-2 variants on the total CD4 + and CD8 + T cell reactivity in infected or vaccinated individuals. Cell Rep Med. 2021 Jul 20;2(7):100355.

- No decreases in CD4 and CD* T cell reactivity in convalescent patients against ancestral strain & several variants of Spike protein AND variants in other protein antigens of the SARS-CoV-2 proteome.
- Those receiving Pfizer/Moderna vaccines, no significant difference in CD4 and CD* T cell reactivity to ancestral & variants strains, EXCEPT, mild decreases (14%, 22%) against B.1.351 (Delta variant). Only looked at Spike protein, not other aspects of virus proteome.

[36] https://www.israelnationalnews.com/News/News.aspx/309762 [published July 13,2021]

- Total of 835,792 Israelis known to have recovered from the virus, 72 instances of re-infection, 0.0086% incidence of people previously infected.
- Vs. >3,000 cases of the 5,193,499 vaccinated Israelis, or 0.0578%.

- Study by Cho A, et al[37]:
  - 5 months after COVID vaccination, individuals observed to have an average 4.7-fold decrease in mean neutralizing activity from their 2-month measurement. Neutralizing antibody activity inversely related with time from vaccination.
  - Additionally, in vaccinated individuals, neutralizing activity against the variants was lower in the variants compared to the original Wuhan Hu-1 strain (looked at: B.1.351 (beta variant), B.1.1.7 (alpha variant), B.1.526 (first isolated in New York City), P.1 (gamma variant) and **B.1.617.2 (delta variant)**. It was 5.7, 1.8, 1.1, 1.4 and **2.7-fold lower** at **2 months**, then even lower at **5 months** by 1.8-, 2.3-, 2.9-, 2.4- and **2.6-fold**, respectively (2.9 lower for original).
  - Looking at memory B cells which provide "rapid recall responses that contribute to long-term protection," convalescent patient had "greater potency and breadth than antibodies elicited by vaccination."
  - No improvement in additional neutralizing activity in vaccinated individual 2 to 5 months after vaccination.
  - Contrary, convalescents showed continued improvement between 1.3 and 6.2 months, some continued to improve further after 1 year (due to increased neutralizing activity in persisting clones).
  - "We conclude that antibody evolution differs in convalescent and vaccinated individuals in that there is less affinity maturation and little increase in breadth between 2 and 5 months after mRNA vaccination."
- UK prospective study of 250 participants (median age 42 years, range 33-52) shows reduced vaccine efficacy (reduced neutralizing antibodies) against the Delta variant (B.1.617.2)[38]
  - Delta variant has 12 mutations in its spike protein relative to Wuhan wild-type.
    - Lacks mutations at amino acid positions 501 or 484 in its ACE2 receptor-binding domain common associated with VOC (variants of concern) or escape from neutralizing antibodies (NAbs).
  - Looked at median time after second vaccination dose of 28 doses from Pfizer vaccine.
  - 3% had no NAb activity at all!
  - 5.8 fold reduced neutralizing antibodies relative to wild-type.
  - Efficacy was decreased over time for the variants—the further away from their second dose of vaccination (8-16 weeks)—decreased Neutralizing antibodies (NAbTs)

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[37] Alice Cho1,*, Frauke Muecksch2,*, Dennis Schaefer-Babajew, et al. Antibody Evolution after SARS-CoV-2 mRNA Vaccination. July 29,2021. Preprint: https://doi.org/10.1101/2021.07.29.454333

[38] Wall EC, Wu M, Harvey R, et al. Neutralising antibody activity against SARS-CoV-2 VOCs B.1.617.2 and B.1.351 by BNT162b2 vaccination. *Lancet*. 2021;397(10292):2331-2333. doi:10.1016/S0140-6736(21)01290-3
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At the very least, I suggest St. Elizabeth allowing concession to those who have evidence of previously having had COVID-19. Demonstrated by a previous +PCR or antigen test for SARS-Cov-2 or positive antibodies or positive T-cell test (https://www.t-detect.com).

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(3) Many Safety Concerns

(i) mRNA encodes for the Spike protein of the virus, this is, unfortunately, the part of the virus that causes the pathogenic effect in its host.

- Spike protein alone impairs endothelial function by downregulation of ACE 2, which is normally protective in the cardiovascular system, and results in inhibiting mitochondrial function.[39]
    - When S protein ("Pseu-Spike") injected into hamsters, saw lung damage and inflammatory infiltration, altered mitochondria dynamics, and damage to vascular endothelial cells.

(ii) mRNA and spike protein injected does not stay at or near the injection site and nearby lymphatics like has been thought to be the case of other vaccines. Accumulate in ovaries, crosses blood-brain barrier.

- The pharmaceutical drug companies (Pfizer, Moderna, J&J) did not report any pharmacodynamic studies of these vaccines as not required for vaccines in the U.S. (although required for drug approval). The presumption is that the mRNA and proteins that are subsequently created stay at or near the injection site like has been thought to be the cause of other vaccines.
- However, Japan demanded Pfizer to do pharmacodynamic studies in animals (mice, rats) prior to release in Japan.
    - FOIA request enabled acquisition of this (partially redacted) report.[40]
    - See table below and link for this report in Japanese. See page 7 and 8—this is in English.
    - Large accumulation of lipid nanoparticle-mRNA in ovaries (progressively accumulates) up to 48 hours (beyond 48 hours not reported).
    - While injection site concentration peaks and decreases, many organs show progressive increase up to 48 hours (not followed beyond this).
    - We do not understand the clinical implications and long-term consequences of this. It needs to be investigated.

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[39] Lei Y, Zhang J, Schiavon CR, He M, et al. SARS-CoV-2 Spike Protein Impairs Endothelial Function via Downregulation of ACE 2. Circulation Research. 2021;128:1323–1326, 31 Mar 2021.

[40] https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

Species (Strain):	Rat (Wistar Han)
Sex/Number of Animals:	Male and female/3 animals/sex/timepoint (21 animals/sex total for the 50 µg dose)
Feeding Condition:	Fed ad libitum
Method of Administration:	Intramuscular injection
Dose:	50 µg [^{3}H]-08-A01-C0 (lot # NC-0552-1)
Number of Doses:	1
Detection:	Radioactivity quantitation using liquid scintillation counting
Sampling Time (hour):	0.25, 1, 2, 4, 8, 24, and 48 hours post-injection

Sample	Mean total lipid concentration (µg lipid equivalent/g (or mL) (males and females combined)							% of administered dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Adipose tissue	0.057	0.100	0.126	0.128	0.093	0.084	0.181	--	--	--	--	--	--	--
Adrenal glands	0.271	1.48	2.72	2.89	6.80	13.8	18.2	0.001	0.007	0.010	0.015	0.035	0.066	0.106
Bladder	0.041	0.130	0.146	0.167	0.148	0.247	0.365	0.000	0.001	0.001	0.001	0.001	0.002	0.002
Bone (femur)	0.091	0.195	0.266	0.276	0.340	0.342	0.687	--	--	--	--	--	--	--
Bone marrow (femur)	0.479	0.960	1.24	1.24	1.84	2.49	3.77	--	--	--	--	--	--	--
Brain	0.045	0.100	0.138	0.115	0.073	0.069	0.068	0.007	0.013	0.020	0.016	0.011	0.010	0.009
Eyes	0.010	0.035	0.052	0.067	0.059	0.091	0.112	0.000	0.001	0.001	0.002	0.002	0.002	0.003
Heart	0.282	1.03	1.40	0.987	0.790	0.451	0.546	0.018	0.056	0.084	0.060	0.042	0.027	0.030
Injection site	128	394	311	338	213	195	165	19.9	52.6	31.6	28.4	21.9	29.1	24.6
Kidneys	0.391	1.16	2.05	0.924	0.590	0.426	0.425	0.050	0.124	0.211	0.109	0.075	0.054	0.057
Large intestine	0.013	0.048	0.093	0.287	0.649	1.10	1.34	0.008	0.025	0.065	0.192	0.405	0.692	0.762
Liver	0.737	4.63	11.0	16.5	26.5	19.2	24.3	0.602	2.87	7.33	11.9	18.1	15.4	16.2
Lung	0.492	1.21	1.83	1.50	1.15	1.04	1.09	0.052	0.101	0.178	0.169	0.122	0.101	0.101

2.6.5.5B. PHARMACOKINETICS: ORGAN DISTRIBUTION CONTINUED

Test Article: [^{3}H]-Labelled LNP-mRNA formulation containing ALC-0315 and ALC-0159
Report Number: 185350

Sample	Total Lipid concentration (µg lipid equivalent/g [or mL]) (males and females combined)							% of Administered Dose (males and females combined)						
	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h	0.25 h	1 h	2 h	4 h	8 h	24 h	48 h
Lymph node (mandibular)	0.064	0.189	0.290	0.408	0.534	0.554	0.727	--	--	--	--	--	--	--
Lymph node (mesenteric)	0.050	0.146	0.530	0.489	0.689	0.985	1.37	--	--	--	--	--	--	--
Muscle	0.021	0.061	0.084	0.103	0.096	0.095	0.192	--	--	--	--	--	--	--
Ovaries (females)	0.104	1.34	1.64	2.34	3.09	5.24	12.3	0.001	0.009	0.008	0.016	0.025	0.037	0.095
Pancreas	0.081	0.207	0.414	0.380	0.294	0.358	0.599	0.003	0.007	0.014	0.015	0.015	0.011	0.019
Pituitary gland	0.339	0.645	0.868	0.854	0.405	0.478	0.694	0.000	0.001	0.001	0.001	0.000	0.000	0.001
Prostate (males)	0.061	0.091	0.128	0.157	0.150	0.183	0.170	0.001	0.001	0.002	0.003	0.003	0.004	0.003
Salivary glands	0.084	0.193	0.255	0.220	0.135	0.170	0.264	0.003	0.007	0.008	0.008	0.005	0.006	0.009
Skin	0.013	0.208	0.159	0.145	0.119	0.157	0.253	--	--	--	--	--	--	--
Small intestine	0.030	0.221	0.476	0.879	1.28	1.30	1.47	0.024	0.130	0.319	0.543	0.776	0.906	0.835
Spinal cord	0.043	0.097	0.169	0.250	0.106	0.085	0.112	0.001	0.002	0.002	0.003	0.001	0.001	0.001
Spleen	0.334	2.47	7.73	10.3	22.1	20.1	23.4	0.013	0.093	0.325	0.385	0.982	0.821	1.03
Stomach	0.017	0.065	0.115	0.144	0.268	0.152	0.215	0.006	0.019	0.034	0.030	0.040	0.037	0.039
Testes (males)	0.031	0.042	0.079	0.129	0.146	0.304	0.320	0.007	0.010	0.017	0.030	0.034	0.074	0.074
Thymus	0.088	0.243	0.340	0.335	0.196	0.207	0.331	0.004	0.007	0.010	0.012	0.008	0.007	0.008
Thyroid	0.155	0.536	0.842	0.851	0.544	0.578	1.00	0.000	0.001	0.001	0.001	0.001	0.001	0.001
Uterus (females)	0.043	0.203	0.305	0.140	0.287	0.289	0.456	0.002	0.011	0.015	0.008	0.016	0.018	0.022
Whole blood	1.97	4.37	5.40	3.05	1.31	0.909	0.420	--	--	--	--	--	--	--
Plasma	3.97	8.13	8.90	6.50	2.36	1.78	0.805	--	--	--	--	--	--	--
Blood:Plasma ratio*	0.815	0.515	0.550	0.510	0.555	0.530	0.540	--	--	--	--	--	--	--

- Moderna study from 2017 states a lipid nanoparticle (LNP)-formulated, modified mRNA vaccine inoculation doesn't stay at injection site in mice, but spreads throughout body. Crosses blood brain barrier, etc.[41]
  - Ovaries not mentioned, but is seen in testes.

[41] Moderna mRNA Vaccine for Influenza Spreads Throughout Body. **Molecular Therapy Vol. 25 No 6 June 2017**
- Greatest in muscle then lymphatic system and spleen, as expected. Also seen in testes, ileum, bone marrow, lung. Trace amounts in brain. See Table 1.

(3) Safety

(iii) There may be some homogeny of the Spike protein to native human tissue (ie: placental tissue), and antibodies created could potentially be a simultaneous target to placental tissue. This is an unknown—it has not been adequately studied. However, there are several legitimate scientists that have put out a call to action to investigate this. We do not know what we do not know.

- In December 2020, Dr. Michael YEADON BSc, Former Vice President & Chief Scientific Officer Allergy & Respiratory at Pfizer Global R&D, and Professor and Dr. Wolfgang Wodarg filed a petition of concern to the Eurpeam Medicines Agency with some specific medical concerns about the vaccination. One of those concerns is that there is a weak, but obvious (to expert reviewers) similarity of the coronavirus spike protein and a family of human proteins called syncytins in both primary amino acid sequence and and their 3-dimensional structure. The Syncytin family of proteins are considered critical for the formation and successful maintenance of the placenta. Therefore, no matter how weak the homology between spike protein and syncytins, the concern arose that, upon making a strong immune response to spike protein, some women might generate an immune response to their own placental proteins. The clinical consequence of this upon fertility and gestation is unknown, and they have demanded this to be further studied.[42]

(3) Safety

(iv) Numbers reported to VAERS are astonishing. The numbers reported far surpass the adverse reactions reported for any other vaccine to-date. The CDC admits they do not have the personnel nor updated technology to adequately follow-up and investigate these reports.
St. Elizabeth Healthcare/Physician's letter states: "The vaccines have been shown to be very effective and safe. Few adverse effects have been reported."
-Question: How is the VAERS (Vaccine Adverse Event Reporting System) explained?

- VAERS COVID Vaccine Data through July 30,2021[43]:
- 545,337 Reports:
  - **12,366 Deaths**
  - 46,036 Hospitalizations
  - 68,040 Urgent Care visits
  - 92,527 Office Visits
  - 4,759 Anaphylaxis
  - 4,044 Bell's Palsy
  - 1,381 Miscarriages
  - 5,236 Heart Attacks
  - 3728 Myocarditis/Pericarditis
  - **14,251 Permanently Disabled**

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[42] https://childrenshealthdefense.eu/eu-issues/covid-19-injections-dangerous-for-mothers-and-babies-building-up-in-ovaries-and-attacking-the-placenta-according-to-former-chief-scientist-of-pfizer-rd/
[43] https://www.openvaers.com/covid-data [Accessed 8/14/21]

  - 2,269 Thrombocytopenia / Low Platelet
  - **12,194 Life Threatening**
  - 23,354 Severe Allergic Reaction
  - 7,509 Shingles
- This is a passive reporting system, so the above numbers are a significant undercount of actual events.
-
- **Other than quoting the CDC's statements that the COVID-19 vaccines are "safe and effective," can St. Elizabeth reference any actual data to back up this statement of safety?
- **What reports have been made and what data analysis has been released explaining the above VAERS numbers reported or any other post-marketing surveillance reports and analysis?
- Comparing myopericarditis reports on VAERS 28 year time period (1990-2018) vs last 6 months (through 6/20/21): 705 reports in 28 years vs 1160 reports in 6 months.[44]

(vi) Mechanism of action of adverse events is postulated to be related to Spike-protein's systemic and inflammatory effects and microthrombosis as is seen in COVID-19 disease combined with the distribution of the spike protein and/or antibodies generated throughout the body.

- 100's of doctors and scientists across the globe have started an organization called "Doctors for COVID Ethics" and are demanding immediate withdrawal of COVID-19 in the absence of crucial safety data and due to the short and longer dangers being observed. They oppose vaccine passports, which place coercive pressure on citizens to submit to dangerous medical experimentation in return for freedoms that once were human rights and violate the Nuremberg Code and other protections.[45]

(4) Widespread vaccination using a non-sterilizing vaccine (vs. targeted population to most vulnerable) during a widespread Pandemic may be contributing to the development of variants.

There is concern among many scientists that wide-spread vaccination during a widespread pandemic is contributing to immune-escape and helping to select for the new variants.

- Ex: Israel: 81% of adult population fully vaccinated (& 59% of overall population), SARS-CoV-2 infections down to <20/day, lifted restrictions 6/1/21, claiming vaccination program "enormously successful," and Prime Minister touted, "Israel is the first country in the world to beat Corona. It's all thanks to our successful vaccination program."[46]

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[44] Bostom, Andrew. Burgeoning Evidence of Myopericarditis After COVID-19 Vaccination in Young People: A Call For Acknowledgment, Pause, and Serious Study, 22 June 2021. https://rationalground.com/burgeoning-evidence-of-myopericarditis-after-covid-19-vaccination-in-young-people-a-call-for-acknowledgment-pause-and-serious-study/

[45] https://doctors4covidethics.org/letters/doctorsforcovidethics-letters/

[46] Mercola. "Highly Vaccinated Israel Has a Nagging Coronavius Problem." https://peckford42.wordpress.com/2021/07/18/highly-vaccinated-israel-has-a-nagging-coronavirus-problemanalysis-by-the-vaccine-reaction-story-at-a-glance-with-81-percent-of-israels-adult-population-fully-vaccinated-against-covid-19-and/

- However, end of June, exponential spike in cases occured, and 6/27/21, restrictions re-imposed. This is despite the lack of border crossings happening in Israel.
- Initially 70% of these new cases were of the Delta variant of the virus.
- Estimated that 40-50% of the new SARS-CoV-2 infections were in previously vaccinated.

This concept is akin to how bacterial antibiotic resistance is developed. Individuals who do not complete antibiotic prescription as prescribed, but only partially treat the bacterial infection, the remaining bacteria "learn" how to evade that antibiotic, and antibiotic-resistant bacteria starts to be selected.

The following concepts are from Dr. Geert Vanden Bossche's writings and videos, which can be seen at: https://www.geertvandenbossche.org

Geert Vanden Bossche, DVM, PhD, "received his DVM from the University of Ghent, Belgium, and his PhD degree in Virology from the University of Hohenheim, Germany. He held adjunct faculty appointments at universities in Belgium and Germany. After his career in Academia, Geert joined several vaccine companies (GSK Biologicals, Novartis Vaccines, Solvay Biologicals) to serve various roles in vaccine R&D as well as in late vaccine development. Geert then moved on to join the Bill & Melinda Gates Foundation's Global Health Discovery team in Seattle (USA) as Senior Program Officer; he then worked with the Global Alliance for Vaccines and Immunization (GAVI) in Geneva as Senior Ebola Program Manager. At GAVI he tracked efforts to develop an Ebola vaccine. He also represented GAVI in fora with other partners, including WHO, to review progress on the fight against Ebola and to build plans for global pandemic preparedness. Back in 2015, Geert scrutinized and questioned the safety of the Ebola vaccine that was used in ring vaccination trials conducted by WHO in Guinea. His critical scientific analysis and report on the data published by WHO in the Lancet in 2015 was sent to all international health and regulatory authorities involved in the Ebola vaccination program. After working for GAVI, Geert joined the German Center for Infection Research in Cologne as Head of the Vaccine Development Office. He is at present primarily serving as a Biotech/ Vaccine consultant while also conducting his own research on Natural Killer cell-based vaccines."

"Massive Population Vaccination during a pandemic of a widely-spread, highly mutable virus using a vaccine that does not sterilize the virus will cause more harm and MUST BE STOPPED. In these circumstances, VACCINATION is causing selection pressure leading to viral immune escape and is contributing to more and more virulent virus strains." (Dr. Geert Vanden Bossche[47] (and below):

- On the surface, one might think that the more people are vaccinated, the fewer people will get infected, and thus less disease transmission. To support this, one can cite that in recent months and weeks the vast majority of patients who have been hospitalized with

[47] https://www.geertvandenbossche.org/post/a-last-word-of-caution-to-all-those-pretending-the-covid-19-pandemic-is-toning-down *Note: A copy of this letter has been sent to WHO, NIH, CDC, the Bill & Melinda Gates Foundation, GAVI, CEPI, FDA, EMEA and to R&D leaders from Pfizer, Moderna, Astra-Zeneca, J&J, Novavax and GSK*

COVID-19 are those who are vaccinated. Therefore, to end the pandemic, a large majority of the population needs to get vaccinated to prevent severe disease, prevent infection, and achieve herd-immunity. However, this logic is flawed and misleading.

- INITIALLY you will see vaccinated individuals and naturally immune individuals (from prior infection) to better clinically with minimal to no clinical disease.
- However, the virus is NOT eradicated from the population as vaccination does not sterilize the virus and continues to circulate in the population.
- All the current vaccines and antibody-based prophylactics target the spike protein receptor-binding domain (RBD) of the SARS-CoV-2 virus. This narrow focus is all directed at Specific immunity to the Spike protein, and very few mutations are required to decrease the affinity for Vaccinal Spike protein antibodies[48,49]. The virus learns in a short time (ie: 2 months or less) how to escape this specific target—"immune escape" of the virus. "The more widely a single epitope is targeted by a biomedical intervention, and the more effective it is, the more rapidly it will generate resistance."[11]
    - Immune escape variants selected because of their capacity to overcome immune pressure have a higher level of infectiousness.
- This contrasts with the natural immunity that develops from natural infection: recovering infection develops nasal and respiratory mucosal response to prevent virus from entering the body (IgA, creates sterilizing immunity). Natural infection also develops more broad immune targets on different aspects of virus proteome, ie: nucleocapsid "N" aspect as well as "S" portion of spike protein; elevated levels of polyreactive, natural viral infections. More broad targets, less pressure to mutate/lose target. Natural immunity (especially in younger population) develops both specific and broad immune targets[50]
    - Note, even the "S-specific" antibodies from natural infection actually have a broader and diversified target epitope compared to vaccination.
- High infectivity rates turn the non-vaccinated breeding ground for increasingly infections variants and transmission of these variants =>
- Because of increased infectiousness & prevalence, viral infection & transmission rates rapidly increase and further erode natural immunity in previously asymptomatically infected individuals (starting with healthy, middle-aged adults and progressively younger and younger individuals). =>

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[48] Van Egeren D, Novokhodko A, Stoddard M, Tran U, Zetter B, Rogers M, et al. (2021) Risk of rapid evolutionary escape from biomedical interventions targeting SARS-CoV-2 spike protein. PLoS ONE 16(4): e0250780. April 28, 2021. https://doi.org/10.1371/journal.pone.0250780

- Study from Harvard shows how targeting one main location (RBD of Spike protein) in context of high viral mutation rates and population pressure, vaccine resistance can develop quickly, even two months, too quickly for a booster to be effective. Calls for diversified molecular targets and therapeutic modalities against SARS-CoV-2.

[49] Garcia-Beltran WF, Lam EC, St Denis K, Nitido AD, Garcia ZH, Hauser BM, Feldman J, Pavlovic MN, Gregory DJ, Poznansky MC, Sigal A, Schmidt AG, Iafrate AJ, Naranbhai V, Balazs AB. Multiple SARS-CoV-2 variants escape neutralization by vaccine-induced humoral immunity. Cell. 2021 Apr 29; 184(9): 2372–2383.e9. https://doi.org/10.1016/j.cell.2021.03.013

[50] Rita Carsetti,a,b Concetta Quintarelli,c,d Isabella Quinti,e Eva Piano Mortari,a Alimuddin Zumla,g Giuseppe Ippolito,h and Franco Locatellic. The immune system of children: the key to understanding SARS-CoV-2 susceptibility? Lancet Child Adolesc Health. 2020 Jun; 4(6): 414–416. Published online 2020 May 6. https://doi.org/10.1016/S2352-4642(20)30135-8

- Increases S-directed immune selection pressure & drives natural selection & possible adaptation of more infectious variants. =>
- High vaccine coverage rates turn exposed vaccination population to a brewery for more viral immune escaping viral variants. =>
- When **variant viruses transmitted to vaccinees, more infectious variants will evolve**, further increasing resistance to and selection for the specific S-directed vaccinal antibodies, as this will have a competitive advantage in vaccinee, being able to reproduce more effectively. =>
- Subsequent transmission of virus immune-escaping variants to non-vaccinated subjects will enable them to rapidly expand in prevalence & replace or dominate previously circulating variants.
- Mass vaccination on a background of enhanced viral infectiousness in a pandemic uses BOTH vaccinated and unvaccinated to speed-up natural selection and immune escape adaptation. This leads to increasing Spike-related mutations with increasing inhibition of vaccine-mediated immunity.
- This is a problem of MASS VACCINATION—the combination of BOTH vaccinated and unvaccinated.
    - Even if everyone vaccinated, vaccines still breeding ground for the virus as it is not eliminated from replication and transmission. Mass vaccination promotes asymptomatic spread of more infectious variants.
    - "Last but not least, it must be emphasized that those calling themselves 'experts' while pretending that this pandemic is 'a pandemic among the non-vaccinated' are devoid of any scientific insight in the evolutionary dynamics of Sars-CoV-2 as currently shaped by a combination of high viral infectivity and vaccine coverage rates. Neither the vaccinated (who merely believed the vaccine would protect them from Covid-19 disease) nor the non-vaccinated (who simply believe there is no need for them to take the vaccine in order to stay protected) are to be blamed for the escalation of this pandemic. Mass vaccination is the one and only culprit." -- Dr. Geert Vanden Bossche[10]
- Are there other scientists who have this concern?
    - "In this context, vaccines that do not provide sterilizing immunity (and therefore continue to permit transmission) will lead to the buildup of large standing popula tions of virus, greatly increasing the risk of immune escape"[11]
    - "Part of the consideration in determining containment measures is the rationale that vaccination will soon stop transmission and allow a return to normality. However, vaccines themselves represent a selection pressure for evolution of vaccine-resistant variants, so the coupling of a policy of permitting high levels of transmission/virus multiplication during vaccine roll-out with the expectation that vaccines will deal with the pandemic, is unrealistic."[51]

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[51] Ruibang Luo, Agnès Delaunay-Moisan, Kenneth Timmis, Antoine Danchin. SARS-CoV-2 biology and variants: anticipation of viral evolution and what needs to be done. Environ Microbiol. 2021 May;23(5):2339-2363. **https://doi.org/10.1111/1462-2920.15487**.

- "Mutations affecting the antigenic phenotype of SARS-CoV-2 will enable variants to circumvent immunity conferred by natural infection or vaccination."[52]

The ever-changing official narrative on Covid-19 vaccines[53]

Official statement/ claims on C-19 vaccine *effectiveness*	Right or wrong?	Supportive evidence
1. C-19 vaccines provide strong protection against (severe) disease	Less and less the case; statement not yet revisited, though	More and more breakthrough cases of disease are being reported
2. C-19 vaccines greatly reduces viral shedding and transmission; there is no need, therefore, to make vaccination mandatory	Wrong; statement had to be changed and vaccines now considered 'the only route to freedom'	It's now generally acknowledged that vaccinees can shed as much as nonvaccinated
3. C-19 vaccines will control pandemic before end 2021; later on changed into 'end 2022'	Wrong; statement meanwhile changed into 'uncertain'	Each new immune escape variant that becomes dominant entails a new pandemic. Phylogenetics-based natural selection analysis clearly indicates faster evolutionary adaptation to rising population-level immune pressure on viral infectiousness (i.e., on spike protein).
4. C-19 vaccines will generate HI upon vaccinating *65%* of the population; later on changed into *70%*, then *80%*, then *90%* and finally into *unlikely achievable*	Wrong; statements had to be changed	Major outbreaks in countries with full vaccination rates between 75-100% (e.g., Iceland, Gibraltar,...) show that HI is *not improbable but impossible*
5. C-19 vaccines make masks for unvaccinated obsolete	Wrong; statement needed to be changed **Note**: although claims on protection from transmission were abandoned, pressure on people to get the shot only increases	Clear evidence provided that also vaccinees can shed substantial amounts of virus. **Note**: Official statistics on percentage of new variants (i.e., carrying new escape mutations) shed by vaccinees as compared to unvaccinated subjects are missing!
6. Seasonal updates of C-19 vaccines will keep pandemic under control and allow to return to a normal life	Scientifically implausible but proposals for seasonal update already on the table	Breakthrough cases and disease (ADE?) already reported in first re-vaccinated cohort in Israel

Prospected effect from C-19 vaccines according to vaccine manufacturers and Public Health authorities as compared to science-based expectations (i.e., taking into account the impact of mass vaccination on the evolutionary dynamics of the pandemic). Deviations from commercial

[52] William T. Harvey, Alessandro M. Carabelli, Ben Jackson,Ravindra K. Gupta, et al. SARS-CoV-2 variants, spike mutations and immune escape. Nat Rev Microbiol. 2021 Jul:19(7):409-424. doi: 10.1038/s41579-021-00573-0.

[53] Bossche, Geert Vanden (blog post). C-19 Pandemia: Quo vadis, homo sapiens? https://www.geertvandenbossche.org/post/c-19-pandemia-quo-vadis-homo-sapiens

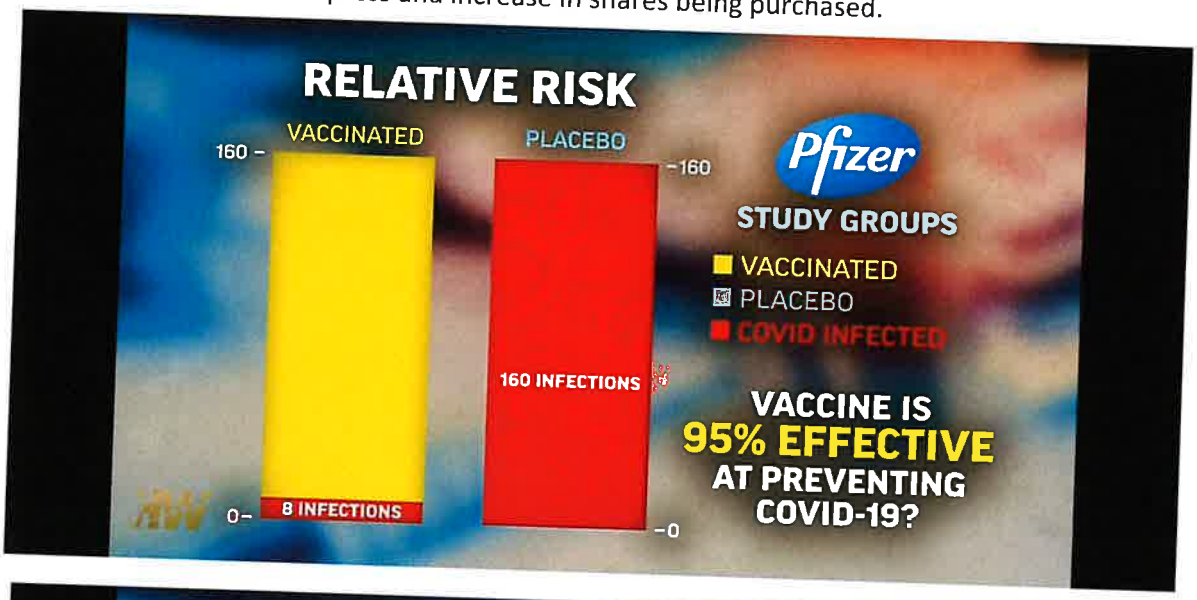
and PH expectations are highlighted in red.[34]

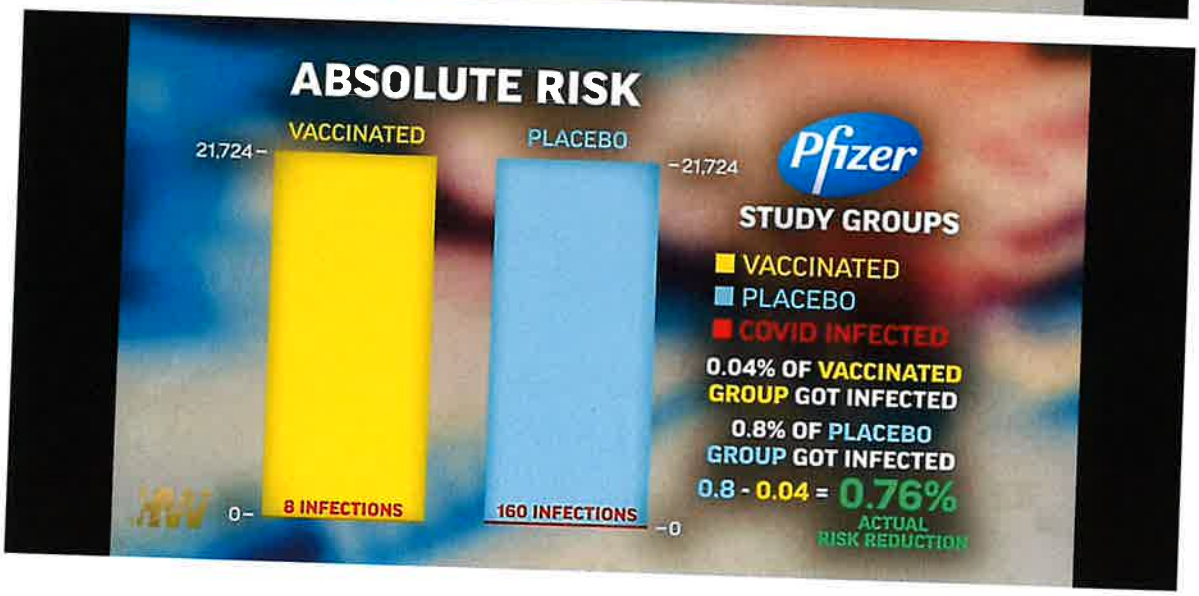
Commercial and Public Health expectations for C-19 Vaccines	Science-based expectations for C-19 vaccines (when deployed for mass vaccination during a pandemic)
1. Protection against disease and diminished viral shedding/ transmission; mass vaccination synergizes with naturally acquired immunity to build robust HI	1. Protection against disease[18] and selection of new, more infectious immune escape variants in vaccinees; asymptomatic shedding by vaccinees prevents HI
↓ 2. Same target product profile maintained through seasonal, variant-matching vaccination	↓ 2. Increased shedding of new, more infectious immune escape variants in vaccinees
	↓ 3. Promoting dominant expansion of new, more infectious immune escape variants ('viral adaptation')
	↓ 4. Diminishing protection against disease, ultimately resulting in higher morbidity and mortality rates than in the unvaccinated
	↓ 5. Promoting dominant expansion of variants harboring new, *neutralization escape* mutations (as, for example, found in lambda variant), resulting in a further increase in morbidity (including ADE?) and mortality rates in vaccinees

(5) Limited data on risk-benefit analysis in general and in mid-age, younger, low-risk adults.

- Absolute risk reduction is not discussed, but this is the more relevant, clinical information. This is the difference between the attack rates with and without the vaccine within the population.
    - Relative Risk Reduction (RRR) considers only participants who could benefit from the vaccine.
    - ARR (and NNV—number need to vaccinate to prevent 1 disease occurrence) are sensitive to background risk—the higher the risk, the higher the effectiveness
    - When reporting only RRR and omitting ARR, reporting bias is present.
- Looking at Pfizer data, reported Relative Risk reduction stated that the vaccine was 95% effective at preventing COVID-19 (note: only to the 2-month mark; only followed for 2 months):
    - They analyzed 160 vaccinated patients—8 of which got infection vs 160 in the placebo arm who got the infection.
    - Math: 8 COVID vax/160 COVID unvax= 0.05% Relative Risk for COVID-19 among vaccinated. Thus, "95% effective at preventing COVID-19."
- Example Pfizer Absolute Risk Reduction can be calculated as follows:
    - Among the 21,724 vaccinated individuals, only 8 were diagnosed with COVID-19. Incidence: 0.04% of vaccinated group got COVID-19.
    - Among the 21,724 placebo individuals, only 160 were diagnosed with COVID-19. Incidence: 0.8% of placebo group got COVID-19.

- Absolute Risk Reduction: 0.8% placebo – 0.04% vaccinated group = 0.76%
- **Absolute Risk Reduction with Pfizer's COVID-19 vaccination for getting COVID-19 only 0.76%.**
  - This obviously does not sound impressive and wouldn't garner much press and increase in shares being purchased.





Another source (Olliaro et al.) calculates the ARR and NNV (slightly different study population numbers used) [54]:

- ARR often ignored because they are less impressive.

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[54] Olliaro P, Torreele E, Vaillant M. COVID-19 vaccine efficacy and effectiveness—the elephant (not) in the room. *Lancet Microbe* 2021; published online April 20. https://doi.org/10.1016/S2666-5247(21)00069-0.

- Moderna ARR is 1.2% and NNV is 81.
- Pfizer ARR is 0.84% and NNV is 119.
- J&J ARR is 1.19% and NNV is 84.

(5) There are promising options for inexpensive, easily accessible treatment that can, and should, be initiated in the outpatient for early treatment and potentially prophylaxis.

- Pfizer posted 7/28/21, "Alongside vaccines, success against #COVID19 will likely require #antiviral treatments for those who contract the virus. We've started a Phase 2/3 trial to evaluate a potential oral therapy that will enroll over 2,000 participants infected with SARS-CoV-2: on.pfizer.com/376FGpl " [they are looking at an IV and po protease inhibitors]

- In preparation of this document, I ran out of time to reference studies on this topic.
- For example, there is some promising data on Fluvoaxmine and Ivermectin, perhaps in combination with other mediations and vitamins.
- If not already in existence, I would be willing to start or be a part of early treatment trials of our St. Elizabeth COVID-19 patients since this is a dire need in our community with this current pandemic. I could start a "COVID Clinic" to treat patients soon after diagnosis. Please let me know if this is something you could potentially support, and I can follow-up with specifics.
  - This would be greatly welcomed and eagerly applauded by the St. Elizabeth community.

(6) No long-term (ie: 1-5 years) information on safety outcomes.

- Cannot compare the mandating of these new COVID-19 vaccination to the mandating of influenza vaccination for healthcare employees.
- The influenza vaccination has been around since 1938 with wide-spread availability in 1945.
- Although always recommended to healthcare workers, locations did not start mandating vaccination until 2008-2009, after 63 years. St. Elizabeth Healthcare only recently mandated influenza vaccination.
- Mandating receipt of a vaccination that has been around 76 years for wide-spread use cannot be compared to a novel vaccination that has been around only less than 1 year, irrespective of FDA approval status.

II. Additional Questions:

What is the end point we are looking for?

- Israel and UK had high % of their population vaccinated, and yet variants emerged and another wave of cases and hospitalizations.
- We will not be able to eradiate this virus with current technology/science. This virus is going to be with us.

- The virus mutations being selected for are more and more infectious. We have not yet seen deleterious mutations of the virus being selected for (ie: less infectivity/virulence).
- Ending the pandemic will require long-lived immunity to SARS-CoV-2 (Cohen, et al.)

III. Suggestions on How to Address Policy Change

My Suggestions on how to graciously change this policy to where St. Elizabeth Healthcare and Physicians can be framed in a positive, admirable light:

- State that decided to change the policy based on recent scientific information that emerged after the mandate announcement.
    - St. Elizabeth prides itself as being up-to-date and on the most recent, best science. And as leaders who respect scientific discovery, we have the humility to pivot when necessary.
    - St. Elizabeth prides itself in being a leader of Healthcare in the region. Proud to set the example for other hospitals to potentially follow.
- Acknowledge the success the vaccine has had to-date. Although there have been breakthrough cases of COVID-19 in vaccinated patients, they represent a small minority of hospitalized patients. This is a great success.
- Desire behind the policy was to create a safe environment for patients and other employees by preventing the spread of SARS-CoV-2 to patients and staff. However, recent data has emerged demonstrating that despite vaccination, for the delta variant, vaccinated and unvaccinated people are able to contract and carry the virus, even unknowingly, to others.
- Since this vaccine does not appear to have a community protection as was once believed and understood, St. Elizabeth Healthcare/Physicians will no longer mandate vaccination for its employees and staff.
- As long as this pandemic is in play, we will continue to do universal masking, do health and temperature screenings, keep sick employees home, and do everything possible to ensure the optimal health for our patients, staff, and community.
- We will continue to educate our providers, nurses, staff, and volunteers on the positive aspects of the COVID-19 vaccines and the success we are seeing as a therapeutic in minimizing disease severity for the individual. We believe through continued education and demonstration of the benefits of the vaccine, transparency in hospitalized numbers re: vaccinated vs unvaccinated patients, more and more staff will elect to protect themselves and choose to get vaccinated as this pandemic continues.
- Again, we pride ourselves in being a leader in this region by "following the science" and acting accordingly. We love our St. Elizabeth employees and patients and want to continue to act in such a way that demonstrates this honor and care.

~~~~~~~~~~~~~~~

You could end here. However, I would encourage you to also consider adding the following below. This would be a fantastic PR opportunity to cast St. Elizabeth in a very favorable light and bring some positive attention to the institution (as well as actually being very beneficial to our patients and community):
~~~~~~~~~~~~~~~

- We are also going to be a leader in the area by being proactive in broadening our therapeutic options by aggressively pursuing additional early therapeutics as an outpatient (*beyond monoclonal antibody infusions... not discussed as much in this paper, there is some decreasing effectiveness b/c this also targets the S-protein, the same area mutations are occurring in the variants*). In addition to outpatient infusions of monoclonal antibodies and Remdesivir, we will also employ protocols using oral medications and important vitamin supplements in the context of clinical investigation to minimize patients that present to the hospital. We will also investigate prophylaxis options in our most vulnerable patients.
- Again, St. Elizabeth Healthcare system seeks to be a leader in the region by doing our part to successfully end this pandemic in an evidence-based, data-driven manner. We hope other hospital systems follow us in suit.

I thank you for your time and your thoughtful consideration. It takes humility to reconsider previous positions in light of new and emerging information. I believe you desire to have Northern Kentucky's best interest in mind.

As a physician within St. Elizabeth Physicians, I consider it my professional duty to have this medical and scientific discussion, even though in the apparent quiet minority. I, too, desire the best for our Northern Kentucky patients, community, and medical staff. I have cited this document heavily to avoid being labeled and quickly dismissed as sharing "misinformation." I would also like to clothe myself with humility and would be open to scientific discussion and considering alternative information.

Respectfully yours,

Amy J. DiChiara, MD
St. Elizabeth Physicians, Gastroenterology

EXHIBIT 3

Forward #2. No reply yet to this one.

[redacted]

Subject: Fwd: Follow-up from our Meeting

From: Amy DiChiara <Amy.DiChiara@stelizabeth.com>
Sent: Thursday, August 26, 2021 2:56 PM
To: Garren Colvin
Subject: Follow-up from our Meeting

Dear Garren,

Thank you for time in meeting with me this last week. I wanted to follow up on a few things we discussed in our meeting about 1.5 week ago now.

1. I wanted to see when you plan on sending out the updated letter you mentioned. When we spoke, you acknowledged the updated scientific information that the COVID-19 vaccinations do not prevent the vaccinated individual from carrying and transmitting the virus unintentionally to patients and other employees. We discussed how the letter sent out to all St. Elizabeth Healthcare and Physician's employees states otherwise: "vaccines will provide strong protection against unintentionally carrying the virus to work and spreading it to patients and peers." Since the stated reason for is no longer accurate, you mentioned your willingness to send a new, updated letter explaining your reasoning for still mandating the vaccine.
2. Have you put any more consideration on supporting the establishment of an outpatient COVID Clinic to allow early treatment of COVID beyond monoclonal antibody infusions to try to prevent hospitalization? Unfortunately, the only thing being done currently is that patients are being told to quarantine, hydrate, and take ibuprofen or acetaminophen. I suggest starting an outpatient treatment protocol based on positive studies suggesting benefit in the literature, and it can be conducted in a clinical-research manner: comparing treatment protocol arm to current standard of care. I think the community would be very proud and happy to hear St. Elizabeth's interest in leading in the community in this way. Again, I would be happy to be involved in this, and I could help recruit other docs to be involved with this as well.
3. I know you mentioned you look to the CDC for your recommendations and guidance. Well, the CDC does not mandate vaccination for their employees, nor do they recommend mandates; therefore, neither should St. Elizabeth Healthcare/Physicians mandate their employees. "The federal government does not mandate (require) vaccination for people. Additionally, CDC does not maintain or monitor a person's vaccination records. Whether a state or local government or employer, for example, can require or mandate COVID-19 vaccination is matter of state or other applicable law."[1]
4. Any further thoughts after having had a chance to read my letter?

I thank you again for your time,

Amy DiChiara

[1] https://www.cdc.gov/coronavirus/2019-ncov/vaccines/facts.html

St. Elizabeth PHYSICIANS

Our Mission:
As a Catholic healthcare ministry, we provide comprehensive and compassionate care that improves the health of the people we serve.

[redacted]

Subject: Email re: FDA approval being misleading

See attached. The outright misleading is disgusting.

[redacted]

Fw: correction for letter

[redacted]

Sat 8/28/2021 1:15 AM

To: Dustin and Amy DiChiara <dustinandamy@hotmail.com>

Here is my request for the honest correction.

----- Forwarded Message -----

From: [redacted]

To: garren.colvin@stelizabeth.com <garren.colvin@stelizabeth.com>; Robert.Prichard@stelizabeth.com <robert.prichard@stelizabeth.com>

Cc: Michele Kenner <michele.kenner@stelizabeth.com>

Sent: Saturday, August 28, 2021, 01:13:15 AM EDT

Subject: correction for letter

Garren and Bob,

I appreciate the letter that was sent earlier on Friday. I noticed a small but important typo that stated the Pfizer BioNTech vaccine has been FDA approved. The BioNTech vaccine has not been fully FDA approved and is still under EUA per the FDA letter (references below), but the new vaccine Comirnaty (same formulation, but legally distinct) has been FDA approved. I sent the email below to Michele Kenner on Wednesday to make sure our staff was properly informed. She did respond that she passed it along to our communication and leadership team. I just want to make sure our staff has the most accurate information as there is a lot of information out there. The correction of this letter with an explanation would be helpful to staff who are uncertain about the FDA approval. I have listed the references to make it easy to find the information. Does St. Elizabeth have Comirnaty vials available for staff? If not, do you know when they will become available for those awaiting the FDA approved vaccine? Thank you very much for looking into this and keeping us informed with the most up to date information. Please let me know if you have any questions.

Here is the FDA site with prescribing information, fact sheets, etc.
https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

Here is the letter of authorization dated 8/23. Please see footnote 8 on page 2 to note the difference.
https://www.fda.gov/media/150386/download

Here is a very helpful fact sheet for healthcare providers that points out the distinction of the EUA BioNTech and the FDA approved Comirnaty.
https://www.fda.gov/media/144413/download

Sincerely,

[redacted]

Michele,

In order to best inform our staff, it should be clarified in the next email that Comirnaty is the only FDA approved vaccine. All other labeled COVID vaccines do not have full FDA approval and are still under EUA. It is my hope our hospital system will have plenty of Comirnaty vials to offer our associates the fully approved FDA vaccine. Thank you, and please let me know if you need any more information or resources.

Sincerely,

[redacted]

From: Amy DiChiara <Amy.DiChiara@stelizabeth.com>
Sent: Friday, August 27, 2021 11:44 PM
To: Amy DiChiara <dustinandamy@hotmail.com>
Subject: Fwd: Follow-up from our meeting

From: Robert Prichard <Robert.Prichard@stelizabeth.com>
Sent: Friday, August 27, 2021 2:14 PM
To: Amy DiChiara
Subject: RE: Follow-up from our meeting

Amy,
Thank you for the follow up.
I did share your document with the SEP Board and with other physicians as well.
Based upon current information, we do not plan to alter our approach at this time. We will continue to monitor new developments as they occur.
I have not done any additional work on a covid clinic at this time. As I am sure you know, we have continued to expand our infusion services for monoclonal antibodies since there is good evidence it is an effective treatment at preventing serious illness and hospitalization.
Bob

From: Amy DiChiara <Amy.DiChiara@stelizabeth.com>
Sent: Thursday, August 26, 2021 3:02 PM
To: Robert Prichard <Robert.Prichard@stelizabeth.com>
Subject: Follow-up from our meeting

Dear Bob,

I wanted to follow-up from our meeting now 1.5 weeks ago where we discussed my concerns about the vaccine mandate imposed upon St. Elizabeth Healthcare and Physician employees.

Have you received any feedback from the physicians you sent my letter to? Do you have any additional responses after having had the opportunity to read my letter? Have you received any additional data you can share with me? In particular, I am interested in any data that has started analyzing the numerous VAERS reports of adverse advents related to the vaccine. I understand the system is passive and anyone can report, but I was hoping there would be some beginnings of analysis reported upon given the number of reports accumulated in the last 8 months. Have you seen any data addressing this? I was disappointed that this data was not presented nor commented upon (from what I can tell per my review) at the FDA hearing of Pfizer's vaccine.

My additional follow-up questions:

- Seeing that there is good scientific evidence for prior infection to COVID providing broad and long-lasting immunity, would you consider allowing exemptions for vaccination as other intuitions are doing?
    - I know you look to large regulatory intuitions for your recommendations. In their Scientific brief from May 10, 2021 entitled "COVID-19 natural immunity," the WHO analyzed the data available re: immunity given prior infection. They summarize many of the same studies I quoted in my letter to you. Their conclusion states, "Current evidence points to most individuals developing strong protective immune responses following natural infection with SARS-CoV-2. . . . recent evidence suggests that natural infection may provide similar protection against symptomatic disease as vaccination, at least for the available follow up period [of 8 months]."[1]

- Have you put any more consideration on supporting the establishment of an outpatient COVID Clinic to allow early treatment of COVID beyond monoclonal antibody infusions to try to prevent hospitalization? This could be done as a video visit primarily, but it could also have an in-person clinic presence as well. Unfortunately, the only thing being done currently is that patients are being told to quarantine, hydrate, and take ibuprofen or acetaminophen at home. I suggest starting an outpatient treatment protocol based on positive studies suggesting benefit in the literature, and it can be conducted in a clinical-research manner: comparing treatment protocol arm to current standard of care. I think the community would be very proud and happy to hear St. Elizabeth's interest in leading in the community in this way. Again, I would be happy to be involved in this, and I could help recruit other docs to be involved with this as well.

- Have you reconsidered the mandate since evidence has come out that the vaccine is primarily an individual therapeutic as it does not prevent the transmission of the virus? Vaccinated individuals can be transmitting the virus asymptomatically just as much as as unvaccinated individuals. And, perhaps the vaccinated will transmit the virus more because they may stay asymptomatic while carrying the virus, or as I have seen often over the last 2 months: the vaccinated individual minimizes their minor symptoms, continuing to work, only to finally test after 2-3 days, discovering they have COVID-19, and had been exposing their co-workers for a few days while actually symptomatic. In contrast, the unvaccinated person is more likely to have symptoms when infected with the virus and thus more likely to quarantine earlier in the disease time-line.
    - If you do not intend to change this mandate, will you at least be sending out updated communication indicating that the reason for the mandate is for individual benefit since new data reveals that the vaccine dose not "provide strong protection against unintentionally carrying the virus to work and spreading it to patients and peers" as was stated in the letter that was sent out?

I thank you, again, for your time and thoughtful considerations.

Amy DiChiara

[1] https://apps.who.int/iris/bitstream/handle/10665/341241/WHO-2019-nCoV-Sci-Brief-Natural-immunity-2021.1-eng.pdf?sequence=3&isAllowed=y

St. Elizabeth PHYSICIANS

Our Mission:

As a Catholic healthcare ministry, we provide comprehensive and compassionate care that improves the health of the people we serve.

AIDET©:

Acknowledge | Introduce | Duration | Explain | Thank

[redacted]

Bonus email:

Info highlighting how mRNA vax goes to ovaries in high concentration. This is in my paper, but thought I'd send it separate b/c the reference is not as widely known, although you may have received it by now.

* The pharmaceutical drug companies (Pfizer, Moderna, J&J) did not report any pharmacodynamic studies of these vaccines as not required for vaccines in the U.S. (although required for drug approval). The presumption is that the mRNA and proteins that are subsequently created stay at or near the injection site like has been thought to be the cause of other vaccines.
* However, Japan demanded Pfizer to do pharmacodynamic studies in animals (mice, rats) prior to release in Japan.
* FOIA request enabled acquisition of this (partially redacted) report.[1]
* See table below and link for this report in Japanese. See page 7 and 8—this is in English.
* Large accumulation of lipid nanoparticle-mRNA in ovaries (progressively accumulates) up to 48 hours (beyond 48 hours not reported).
* While injection site concentration peaks and decreases, many organs show progressive increase up to 48 hours (not followed beyond this).

Feel free to share widely.

[redacted]

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[1] https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf

The SARS-CoV-2 Delta variant is poised to acquire complete resistance to wild-type spike vaccines

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Abstract:
mRNA-based vaccines provide effective protection against most common SARS-CoV-2 variants. However, identifying likely breakthrough variants is critical for future vaccine development. Here, we found that the Delta variant completely escaped from anti-N-terminal domain (NTD) neutralizing antibodies, while increasing responsiveness to anti-NTD infectivity-enhancing antibodies. Although Pfizer-BioNTech BNT162b2-immune sera neutralized the Delta variant, when four common mutations were introduced into the receptor binding domain (RBD) of the Delta variant (Delta 4+), some BNT162b2-immune sera lost neutralizing activity and enhanced the infectivity. Unique mutations in the Delta NTD were involved in the enhanced infectivity by the BNT162b2-immune sera. Sera of mice immunized by Delta spike, but not wild-type spike, consistently neutralized the Delta 4+ variant without enhancing infectivity. Given the fact that a Delta variant with three similar RBD mutations has already emerged according to the GISAID database, it is necessary to develop vaccines that protect against such complete breakthrough variants.

Introduction

Newly developed mRNA-based vaccines for SARS-CoV-2 have proven to be quite effective in preventing infection as well as severe COVID-19 (Jackson et al., 2020; Polack et al., 2020). However, new SARS-CoV-2 variants have repeatedly appeared and spread within the human population. Recent variants have acquired numerous mutations throughout the genome and are highly infectious compared to the original SARS-CoV-2. Although the spike protein used in currently approved mRNA-based vaccines consists of the original spike protein without mutations, these vaccines are nonetheless effective against variants of concern (VOC) (Collier et al., 2021; McCallum et al., 2021; Muik et al., 2021; Wang et al., 2021b). The receptor binding domain (RBD) of the spike protein binds to the host cell receptor ACE2, and the interaction mediates membrane fusion during SARS-CoV-2 infection (Hoffmann et al., 2020). Neutralizing antibodies against SARS-CoV-2 are mainly directed to the RBD and block the interaction between the RBD and ACE2. Most SARS-CoV-2 variants have acquired mutations in the neutralizing antibody epitopes of the RBD, resulting in escape from neutralizing antibodies (Cele et al., 2021; Collier et al., 2021; Davies et al., 2021; Madhi et al., 2021; Planas et al., 2021a; Tegally et al., 2021; Wang et al., 2021a). However, mutations in the RBD also tend to affect binding to ACE2. Therefore, there is a tradeoff in the evolution of the RBD between mutations that maintain ACE2 binding while escaping the recognition by neutralizing antibodies. In addition, mRNA vaccine-immune sera contain various neutralizing antibodies that recognize epitopes in different parts of the spike protein. It is an important to ascertain whether SARS-CoV-2 variants are likely to emerge that are completely resistant to immunity induced by the current mRNA-based vaccines. Vigilance against such resistant variants is essential for development of next-generation vaccines.

The SARS-CoV-2 Delta variant (B.1.617.2) is highly contagious and is rapidly spreading (Callaway, 2021). The neutralizing activity of sera from vaccinated individuals as well as convalescent COVID-19 patients decreases for the Delta variant compared to the wild-type (Liu et al., 2021a; Planas et al., 2021b). The Delta variant has several mutations in both the N-terminal domain (NTD) and RBD. The L452R and T478K mutations in the RBD of the Delta variant are also observed in other variants that are not as infectious as the Delta variant. Therefore, mutations in the RBD alone do not explain the high infectivity of the Delta variant. In contrast, among Delta mutations, several substitutions or deletions in the NTD—T19R, G142D, E156G, F157del and R158del—have not been observed in other major variants. This suggests that mutations in the NTD may play a key role in the high infectivity of the Delta variant. Although anti-RBD antibodies are thought to play a dominant role in vaccine-induced immunity against SARS-CoV-2 (Robbiani et

al., 2020), neutralizing antibodies directed against the NTD are also important for SARS-CoV-2 neutralization (Chi et al., 2020; Li et al., 2021; Liu et al., 2020; Suryadevara et al., 2021; Voss et al., 2021). Moreover, we and others have recently demonstrated that antibodies against a specific site on the NTD can enhance the infectivity of SARS-CoV-2 by inducing the open form of the RBD (Li et al., 2021; Liu et al., 2021b). Therefore, it is important to elucidate the function of both the neutralizing and enhancing antibodies in order to understand the pathogenicity of the emerging SARS-CoV-2 variants. In this study, in order to understand the mechanism of the Delta variant's high infectivity, we systematically examined Delta variant mutations in the NTD and RBD and suggest an evolutionary pathway by which the Delta variant could achieve complete escape from vaccine-induced immunity, which provides important information for the design of next-generation vaccines.

Results

Neutralizing activity of anti-NTD and anti-RBD monoclonal antibodies from COVID-19 patients against the Delta variant.

In order to understand the mechanism underlying the increased infectivity of the SARS-CoV-2 Delta variant, we analyzed the binding of various types of anti-spike monoclonal antibodies obtained from COVID-19 patients to the Delta spike protein **(Figure 1A)**. Because these monoclonal antibodies were obtained from patients infected in mid-2020, at a time when the SARS-CoV-2 variants had not yet emerged, it is likely that they were elicited by the same wild-type spike protein as is used in current vaccines (Brouwer et al., 2020; Chi et al., 2020; Li et al., 2021; Robbiani et al., 2020; Suryadevara et al., 2021; Zost et al., 2020). Most neutralizing antibodies are directed against the RBD, and the Delta variant has two mutations in this domain, L452R and T478K. L452 has been reported to be an epitope for some, but not most, neutralizing antibodies (McCallum et al., 2021; Wang et al., 2021b). T478K is located in the ACE2 binding site and appears to be mainly involved in increased ACE2 binding affinity (Xu et al., 2021). In our analysis of various anti-RBD antibodies, we found that only a few of the neutralizing antibodies failed to recognize the Delta spike, while most anti-RBD neutralizing antibodies bound to Delta spike at levels comparable to wild-type spike **(Figure 1A)**.

The Delta variant possesses several unique mutations in the NTD—T19R, G142D, E156G, F157del and R158del—suggesting the possibility that binding of some anti-NTD neutralizing antibodies elicited by wild-type spike could be disrupted. In addition to the 13 published anti-NTD neutralizing antibodies (Chi et al., 2020; Li et al., 2021 ; Liu et al., 2020; Suryadevara et al., 2021; Voss et al., 2021), we found that COV2-2016, COV2-2026 and COV2-2150 are also anti-NTD neutralizing antibodies for wild-type spike **(Figure 1B)**. We analyzed these 16 anti-NTD neutralizing antibodies, and found that none of the anti-NTD neutralizing antibodies could recognize Delta spike **(Figure 1A)**. In contrast, when we analyzed the binding of the anti-NTD infectivity-enhancing antibodoies (Li et al., 2021; Liu et al., 2021b), eight out of ten anti-NTD enhancing antibodies bound to Delta spike at levels comparable with wild-type spike **(Figure 1A)**. Some of the anti-NTD antibodies that were not well characterized as either neutralizing/enhancing antibodies showed partial or complete reduction in binding to Delta spike compared to wild-type spike, while others showed strong binding. The high frequency of reduced or enhanced recognition by anti-NTD antibodies against the Delta variant suggests that the antigenicity of the NTD has been greatly affected by mutations in the NTD.

Next, we analyzed the function of the enhancing and neutralizing antibodies on the Delta variants using pseudovirus bearing either the Delta spike protein (Delta pseudovirus) or wild-type spike (wild-type pseudovirus) **(Figure 1B-1D)**. The viral titer of each pseudovirus was checked by its infectivity to HEK293T cells transfected with ACE2 (**Figure S1**). Anti-RBD neutralizing antibodies that bound to the Delta spike completely neutralized the infection of either Delta or

wild-type pseudovirus **(Figure 1C)**. All anti-NTD neutralizing antibodies we tested failed to recognize the Delta spike protein **(Figure 1A)**. As expected, these anti-NTD antibodies did not neutralize infection by the Delta pseudovirus, whereas they decreased the infectivity of the wild-type pseudovirus **(Figure 1B)**. The neutralizing efficiency of anti-NTD neutralizing antibodies against the wild-type pseudovirus was lower than that of anti-RBD neutralizing antibodies, as previously reported (Chi et al., 2020; Li et al., 2021 ; Liu et al., 2020; Suryadevara et al., 2021; Voss et al., 2021). Enhancing antibodies increase the infectivity of SARS-CoV-2 by inducing the open form of the RBD (Liu et al., 2021b). As described above, the recognition by most of the enhancing antibodies was well conserved in the Delta variant **(Figure 1A)**. When the effect of the enhancing antibodies was analyzed, the infectivity enhancement of the Delta pseudovirus by some of the enhancing antibodies was more than that of the wild-type pseudovirus **(Figure 1D)**. These data suggested that the Delta variant completely escaped from anti-NTD neutralizing antibodies while maintaining functional enhancing antibody epitopes. Because the enhancing antibodies decrease the effect of anti-RBD neutralizing antibodies (Li et al., 2021; Liu et al., 2021b), there is a possibility that the Delta variant maintains the infectivity in the presence of anti-RBD neutralizing antibodies as a result of enhancing antibodies.

Neutralizing activity of BNT162b2-immune sera against Delta variants.

We next analyzed the neutralizing activity of twenty sera from healthy individuals fully immunized with Pfizer-BioNTech BNT162b2 mRNA vaccine against the Delta pseudovirus **(Figure 2A)**. Although most of BNT162b2-immune sera completely blocked the infection of the Delta pseudovirus at high concentration, the neutralizing titer of BNT162b2-immune sera against Delta pseudovirus decreased significantly compared to wild-type pseudovirus **(Figure 2B)**, similar to a previous report (Liu et al., 2021a; Planas et al., 2021b). Because none of the anti-NTD neutralizing antibodies were effective against the Delta variant **(Figure 1A and 1B)**, it is likely that anti-RBD neutralizing antibodies play a major role in the neutralizing activity of BNT162b2-immune sera against the Delta variant.

To elucidate the contribution of the NTD and RBD in the resistance of the BNT162b2-immune sera against the Delta variant, we generated chimeric spike proteins in which the NTD, RBD or S2 subunit was encoded by either the wild-type (W) or Delta (D) variant **(Figure 3A)**. Anti-NTD enhancing antibody, COV2-2490, binds to both the wild-type and Delta NTD, whereas anti-NTD neutralizing antibody, 4A8, binds to the wild-type NTD but not Delta NTD. Similarly, Anti-RBD neutralizing antibody, C144, binds to both the wild-type and Delta RBD, whereas anti-RBD neutralizing antibody, C002, binds to the wild-type RBD but not Delta RBD. As expected, C002 bound well to spike with the wild-type RBD (WWD or DWD) but weakly to spike with Delta RBD (DDD or WDD) **(Figure S2)**. Similarly, anti-NTD neutralizing antibody, 4A8, bound to spike with the wild-type NTD (WWD or WDD) but failed to bind to spike with the Delta NTD (DDD or DWD). COV2-2490 and C144 bound to all of the chimeric spike proteins. These data suggest that each domain of the chimeric spike proteins retains its original antigenicity.

We next generated pseudovirus containing these recombinant spike proteins and analyzed the effect of BNT162b2-immune sera. The neutralizing activity of the BNT162b2-immune sera against WWD pseudovirus decreased slightly compared to that of wild-type pseudovirus (WWW), suggesting that mutations in the S2 domain are involved in the resistance of the Delta variant **(Figure 3B and 3C)**. When infectivity of DWD pseudovirus, in which wild-type NTD was substituted to the Delta NTD, was compared with WWD pseudovirus, the neutralizing activity of BNT162b2-immune sera significantly decreased further. The neutralizing activity of the BNT162b2 immune sera was reduced against WDD pseudovirus, in which wild-type RBD was replaced by Delta RBD, compared to DWD pseudovirus. The neutralizing activity of the BNT162b2-immune sera decreased further against Delta pseudovirus (DDD). These data suggest

that both NTD and RBD mutations in the Delta spike are involved in the resistance of the BNT162b2-immune sera against the Delta variant.

Cryo-EM analysis of the Delta spike

All anti-NTD monoclonal neutralizing antibodies from COVID-19 patients failed to bind to Delta spike whereas most of the enhancing antibodies maintained reactivity to Delta spike (**Figure 1A**). Although there are several mutations in the NTD of Delta spike, known epitopes for anti-NTD neutralizing antibodies are conserved in the Delta variant. To evaluate the effect of mutations in the Delta variant on anti-NTD neutralizing antibody epitope structure, single particle cryo-EM analysis was employed. Data were analyzed by heterogenous refinement and *ab-initio* reconstruction followed by non-uniform refinement. As a result, a density map of the spike protein was obtained at 3.1 Å resolution **(Figure S3 and Table S1)**. To build an atomic model of the spike, we predicted the structures of the Delta variant NTD using AlphaFold2 (Jumper et al., 2021). The predicted NTD model of the Delta variant was used as an initial model for fitting into the obtained map. The statistics of the model of the Delta variant spike are summarized in **Table S1**. When the NTD models of Delta variant and wild-type spike were compared, the major epitope residues for the enhancing antibody—H64, W66, V213 and R214—were structurally well conserved (**Figure 4**). In contrast, a large conformational change was observed in the residues of anti-NTD neutralizing antibody epitopes **(Figure 4)**. The maximum interatomic distance between the Delta variant and the wild-type was more than 9 Å **(Figure 4B)**. In the NTD of the Delta variant, the β strands containing four epitope residues—Y144, K147, K150 and W152—were shortened and shifted significantly compared to the wild-type **(Figure 4A)**. These structural changes were most likely caused by deletion of F157 and R158. As a result, these four residues were quite different from the wild type. R246 and W258 showed large changes compared to the wild-type **(Figure 4)**, and the loop connecting these two residues appeared to be highly flexible. These data suggest that dramatic changes in the structure of the anti-NTD neutralizing antibody epitope residues are responsible for the complete loss of reactivity to anti-NTD neutralizing antibodies against the Delta spike.

Prediction of possible future mutations of the Delta variant

The Delta variant became completely resistant to anti-NTD neutralizing antibodies in the BNT162b2 immune serum by acquiring mutations in the NTD, and thus anti-RBD neutralizing antibodies seem to be mainly responsible for the neutralizing activity in the BNT162b2 immune sera **(Figure 1, Figure 2 and Figure 3)**. These results suggest that the Delta variant may acquire full resistance to BNT162b2 immune sera by acquiring additional mutations in the RBD that disrupt recognition of anti-RBD neutralizing antibodies. Indeed, a Delta variant that has acquired the K417N mutation in the RBD, known as AY.1 (Delta plus), has already emerged and its frequency in the general population is increasing (Gupta et al., 2021). To investigate the potential occurrence of additional mutations, we analyzed the additive effects of mutations acquired by the Delta variant in the GISAID database (**Figure S4**). The Delta variant has already acquired large numbers of additional mutations in the RBD, some of which occur in epitopes for anti-RBD neutralizing antibodies (Greaney et al., 2021a; Greaney et al., 2021b; Greaney et al., 2021c; Wang et al., 2021b; Weisblum et al., 2020). In addition to the K417N mutation, Delta variants with E484K, F490 or N501Y mutations—observed in the Alpha, Beta, Gamma and/or Lambda variants—are also increasing **(Figure 5A)**. Considering the very rapid increase in the population of people infected with the Delta variant, the Delta variant is likely to acquire further mutations in infected people, and those with further increased infectivity will be selected. Indeed, the Delta variant with multiple mutations in anti-RBD neutralizing antibody epitopes have already emerged according to the GISAID database **(Figure 5B)**. In particular, EPI_ISL_2958474 possesses three additional

mutations in anti-RBD neutralizing antibody epitopes, although the NTD sequence is not identical to the representative Delta variant. Accordingly, we analyzed the effect of major mutations observed in SARS-CoV-2 variants on the RBD of the Delta variant (**Figure 5C**). Because the Delta variant contains the T478K mutation and neighboring residues may show similar effects, the S477N mutation was excluded. Accordingly, we introduced four mutations in the Delta spike (Delta 4+)—K417N, N439K, E484K and N501Y—and analyzed the effect of these mutations (**Figure 5D**).

Enhanced infectivity of the Delta 4+ pseudovirus by some BNT162b2-immune sera.

We analyzed the binding of several anti-RBD neutralizing antibodies to the Delta spike with a single additional mutation or multiple mutations in the RBD (**Figure 6A**). Most anti-RBD antibodies recognized Delta spike with a single additional mutation, but not the Delta 4+ spike protein. The C135 anti-RBD neutralizing antibody, whose major epitopes are R346 and N440 (Greaney et al., 2021b; Weisblum et al., 2020), still recognized the Delta 4+ spike. We then generated pseudovirus bearing mutant spike proteins. The Delta pseudovirus with additional single RBD mutations was slightly more resistant to BNT162b2-immune sera (**Figure 6B**). The effects of the single additional mutations were slightly different depending on the individuals, although infection was completely blocked at the highest concentration of the serum. Next, we analyzed the Delta 4+ pseudovirus with four additional RBD mutations (**Figure 6C**). Surprisingly, most BNT162b2-immune sera enhanced infectivity of the Delta 4+ pseudovirus in a dose-dependent manner at relatively low concentrations of BNT162b2-immune sera, but showed weak neutralization only at the highest concentration of the sera (**Figure 6D and 6E**). Especially, PFZ7 greatly enhanced the infectivity at relatively low serum concentration. Some sera, such as PFZ13 and PFZ14, did not show neutralizing activity even at the highest concentration of the sera. The neutralizing titers of PFZ13 and PFZ14 against wild-type or Delta variant were apparently lower than others (**Figure 2A**). On the other hand, PFZ15 effectively neutralized the Delta 4+ pseudovirus, but the neutralizing titers of PFZ15 against the wild type and Delta variant were not particularly high compared to the others. Because most neutralizing antibodies against either NTD or RBD do not work for the Delta 4+ pseudovirus, while most enhancing antibodies remain functional for the Delta 4+ pseudovirus, the increased infectivity in the presence of BNT162b2-immune sera appears to be mediated by anti-NTD enhancing antibodies.

In order to analyze the contribution of Delta NTD to the enhanced infectivity, we generated pseudovirus bearing spike protein with wild-type NTD and Delta 4+ RBD (**Figure 6C**). Although some BNT162b2-immune sera enhanced infectivity of the Delta 4+ pseudovirus, the Delta 4+ virus with wild-type NTD did not show enhanced infectivity by BNT162b2-immune sera (**Figure 6D and 6E**). These data suggested that mutations in the NTD of the Delta variant made the virus more susceptible than the wild-type to anti-NTD enhancing antibodies in BNT162b2-immune sera, and thus reduced the neutralizing effect of anti-RBD neutralizing antibodies.

Sera from the Delta spike immunized mice do not show enhanced infectivity against Delta 4+ pseudovirus.

Because wild-type spike was used for BNT162b2 mRNA vaccine, the enhanced infectivity of the Delta 4+ pseudovirus by some BNT162b2-immune sera appears to be caused by the decreased neutralizing antibody titer of anti-NTD and anti-RBD neutralizing antibodies against Delta 4+ pseudovirus. Therefore, neutralizing antibody titers against the Delta variants may be relatively high compared to enhancing antibodies when immunizing with the Delta spike, even though the enhancing antibody epitopes are conserved in the Delta spike protein. To test the effect of immunization by Delta spike, we immunized mice with B16F10 mouse melanoma cells transiently transfected with wild-type or Delta spike protein (**Figure 7A**). We used B16F10 cells because the

immunogenicity of B16F10 melanoma cell line is quite low (Priem et al., 2020). In addition, the conformation of spike protein expressed on transfectants is likely to be similar to that of spike protein expressed by mRNA vaccines. All mice effectively produced antibodies against spike protein (**Figure S5**). The wild-type spike immunized sera neutralized wild-type pseudovirus well, whereas the neutralizing effect against the Delta pseudovirus decreased, similar to BNT162b2-immune sera (**Figure 7B and 7C**). In contrast, Delta spike immunized sera neutralized both wild-type and Delta pseudovirus well. Just one mouse produced antibodies that neutralize the Delta pseudovirus better than wild-type pseudovirus. When we analyzed the Delta-4+ pseudovirus, some sera from wild-type spike immunized mice showed enhanced infectivity in a dose dependent manner at relatively low concentrations of sera similar to some BNT162b2-immune sera (**Figure 7D and 7E**). Especially, #w1 mouse serum showed enhanced infectivity at any concentration, although the same serum neutralized the wild-type pseudovirus well. In contrast, the enhanced infectivity by immunized sera was not observed when the Delta spike was used for immunization. Sera from the Delta-spike immunized mice did not exhibit enhanced infectivity at any concentration of sera. These data suggest that vaccines containing the Delta, but not wild-type, spike might be required to control the Delta subvariant that may emerge in the future.

Discussion

The Delta variant is highly contagious and breakthrough infection to fully vaccinated individuals is often observed (Lopez Bernal et al., 2021), suggesting that neutralizing antibodies in fully vaccinated individuals are not sufficient to protect against infection by the Delta variant. Anti-RBD antibodies are thought to play a major role in protection against SARS-CoV-2 infection. The Delta variant has L452R and T478K mutations in the RBD, and L452 has been shown to be an epitope for some neutralizing antibodies (McCallum et al., 2021; Wang et al., 2021b). However, most neutralizing antibodies bound to the Delta RBD and neutralized the infection. Therefore, mutations in the RBD alone may not explain the decreased neutralizing titers of the BNT162b2-immune sera against the Delta variant.

The Delta variant has multiple mutations in the NTD: T19R, G142D, E156G, F157del and R158del. All anti-NTD neutralizing antibodies failed to recognize the Delta spike, indicating that the Delta variant is completely resistant to anti-NTD neutralizing antibodies elicited by wild-type spike protein, which is the antigenic component of widely used mRNA vaccines. In contrast, most anti-NTD enhancing antibodies recognized Delta spike at the same level as wild-type spike, and some anti-NTD enhancing antibodies exhibited increased infectivity enhancement by Delta pseudovirus compared to wild-type pseudovirus. Consistent with this observation, the structures of enhancing anti-NTD antibody epitopes were well conserved with the wild type. Because enhancing antibodies reduced neutralizing activity of anti-RBD neutralizing antibodies (Li et al., 2021; Liu et al., 2021b), mutations in the NTD may play an important role in the resistance of the Delta variant to the BNT162b2-immune sera. Indeed, a Delta pseudovirus with wild-type NTD was more susceptible to neutralization by BNT162b2-immune sera than full Delta pseudovirus. The effect of the Delta NTD was more obvious for the Delta 4+ pseudovirus. These data indicated that mutations in the NTD are involved in the escape of SARS-CoV-2 from neutralizing antibodies. It is likely that the mutations in the NTD that abrogate neutralizing antibody binding while retaining enhancing antibody binding are beneficial to the virus. These mutations in the Delta variant may suggest adaptation to the presence of enhancing antibodies while maintaining evasion of anti-NTD and anti-RBD neutralizing antibodies in immunized or previously infected hosts.

Not only Delta, but also other VOCs such as Alpha (B.1.1.7), Beta (B.1.135), and Gamma (P.1) show more mutations in the NTD than in the RBD. Because the NTD is involved in the regulation of the conformation of the RBD but not in direct binding to the host receptor ACE2 (Liu et al., 2021b), it can tolerate many mutations. As with the Delta variant, most anti-NTD neutralizing

antibodies have been reported not to bind to the Alpha and Beta variants (Voss et al., 2021; Wang et al., 2021a). Recently, L-SIGN has been reported to be an entry receptor for SARS-CoV-2 (Amraei et al., 2021; Kondo et al., 2021; Soh et al., 2020; Thepaut et al., 2021). L-SIGN specifically bound to NTD but not RBD of SARS-CoV-2 spike protein and mediated SARS-CoV-2 infection of non-ACE2 expressing cells by inducing membrane fusion (Soh et al., 2020). Furthermore, anti-NTD neutralizing antibodies efficiently blocked SARS-CoV-2 infection of L-SIGN-expressing cells compared to that of ACE2-expressing cells. Considering the fact that most VOCs have completely escaped from anti-NTD neutralizing antibodies regardless of the fact that the neutralizing efficiency is quite low compared to anti-RBD neutralizing antibodies *in vitro*, SARS-CoV-2 infection mediated by the NTD through L-SIGN or other unknown receptors may play a more important role *in vivo* than *in vitro*. Further analyses of function of NTD as well as anti-NTD neutralizing antibodies are required to elucidate the pathogenicity of SARS-CoV-2.

The enhancing antibodies bind to a specific site on the NTD, inducing the open form of the RBD, which increases the affinity of spike protein to ACE2 (Liu et al., 2021b). Recently, it has been reported that the enhancing antibodies do not increase the infectivity *in vivo* (Li et al., 2021). However, only one human IgG1 monoclonal enhancing antibody, among 11 known enhancing antibodies, has been tested *in vivo*. The affinities and epitopes of enhancing antibodies to the NTD, as well as the IgG subclass of enhancing antibodies, may affect their *in vivo* function. Recently, it has been reported that binding of neutralizing antibodies to Fc receptors is required for their neutralizing activity *in vivo* (Schafer et al., 2021; Suryadevara et al., 2021; Winkler et al., 2021). Indeed, IgG1, which is the most frequently used antibody subclass in *in vivo* studies, has the strongest affinity for Fc receptors and shows strong effector function; whereas, IgG2 and IgG4 weakly bind to Fc receptors (Nimmerjahn and Ravetch, 2008). Therefore, it is likely that the *in vivo* function of anti-NTD enhancing antibodies will vary depending on the antibody subclass, the specific variable region sequence, or both. Given the fact that the Delta variant maintained enhancing antibody epitopes and is more sensitive to enhancing antibodies, it is likely that the enhancing antibodies are involved in augmentation of the SARS-CoV-2 infectivity *in vivo*.

Several BNT162b2 immune sera showed neutralizing activity against the Delta 4+ pseudovirus at a 1:10 dilution, but conversely increased infectivity at 1:30 dilution. In general, the activity of neutralizing antibodies does not change so drastically with a three-fold difference in concentration. Therefore, the effect of the BNT162b2 immune sera against the Delta 4+ pseudovirus cannot be explained simply by the concentration of neutralizing antibodies. The BNT162b2 immune sera did not show enhanced infectivity against the Delta 4+ pseudovirus with wild-type NTD at any serum concentration. Since the effect of anti-NTD infectivity-enhancing monoclonal antibodies is affected by the concentration of anti-RBD neutralizing antibodies (Li et al., 2021; Liu et al., 2021b), the effect of infectivity-enhancing antibodies in BNT162b2 immune sera is likely to be more pronounced when the concentration of anti-RBD neutralizing antibodies falls below a certain threshold. Indeed, the BNT162b2 immune sera with low neutralizing titers against the Delta pseudovirus showed enhancement against the Delta 4+ pseudovirus even at high serum concentration. Although the neutralizing antibody titer is the highest three weeks after the second immunization, it gradually decreases (Doria-Rose et al., 2021; Widge et al., 2021). As in the case of diluted sera, it is possible that the effect of infectivity-enhancing antibodies may become more evident some time after immunization, even if the neutralizing and enhancing antibody titers decrease equally. In addition, neutralizing antibody titers induced by adenovirus vaccines and inactivated vaccines are lower than those induced by mRNA vaccines (Lim et al., 2021; Shrotri et al., 2021). Therefore, there is a possibility that the enhancing effect might be more pronounced against the Delta 4+ pseudovirus with immune sera of adenovirus vaccines or inactivated vaccines, similar to BNT162b2 immune sera with low neutralizing titers. On the other hand, some BNT162b2 immune sera did not enhance infection of Delta 4+ pseudovirus at any serum concentration and

neutralized well. Similarly, despite the use of inbred mice, the effect of sera on the infectivity of Delta 4+ pseudovirus varied greatly among individual mice immunized with the wild-type spike. The sera of some mice showed enhancement of the Delta 4+ pseudovirus infection, while others showed neutralization at any serum concentration. The delicate balance of antibody titer, affinity, or epitope between neutralizing and enhancing antibodies might affect the effect of sera on the infectivity. It is important to further analyze the characteristics of neutralizing and enhancing antibodies produced after immunization.

SARS-CoV-2 has acquired a number of mutations to date, which have arisen within infected individuals. Therefore, new variants are likely to emerge more frequently in situations where many people are infected. Because the Delta variant is spreading so explosively, it has already acquired numerous additional mutations in the spike protein coding region, suggesting that the Delta variant will continue to acquire further mutations. Some mutations observed in the RBD of the Delta variant have been reported to be epitopes for anti-RBD neutralizing antibodies (Greaney et al., 2021a; Greaney et al., 2021b; Wang et al., 2021b). Newly emerged variants that adapt to the environment of their host's immune system will be selected and expand. The Delta variant with 4 additional mutations in the RBD were not neutralized by most BNT162b2-immune sera because of unique mutations in the NTD. More importantly, infectivity of the Delta 4+ was enhanced by some BNT162b2-immune sera. Furthermore, of the four additional mutations, a Delta variant with three mutations has already been registered in the GISAID database; it is likely that a Delta variant that has acquired five mutations in the RBD in total will acquire additional mutations in the near future. Although we have selected K417N, N439K, E484K, and N501Y as additional mutations for the Delta variant, other combinations of anti-RBD neutralizing epitopes can be expected to have similar or stronger effects than the Delta 4+ variant. Indeed, the Delta 4+ still possess R346, one of major epitope residues for anti-RBD neutralizing antibodies such as C135. Given the current high mutation rate of SARS-CoV-2, predicting emerging spike mutations is very important to develop effective vaccines against emerging SARS-CoV-2 variants. Immunization by dangerous spike protein variants that are likely to emerge in the future may be effective in preventing the emergence of such variants.

A third round of booster immunization with the SARS-CoV-2 vaccine is currently under consideration. Our data suggest that repeated immunization with the wild-type spike may not be effective in controlling the newly emerging Delta variants. We demonstrated that immunization by Delta spike induces antibodies that neutralize not only the Delta variant but also wild-type and the Delta 4+ variant without enhancing the infectivity. Although mRNA vaccination may yield different results from our animal model, development of mRNA vaccine expressing the Delta spike might be effective for controlling the emerging Delta variant. However, epitopes of the enhancing antibodies, not neutralizing antibodies, are well conserved in most SARS-CoV-2 variants, including the Delta variant. Therefore, additional immunization of the spike protein derived from SARS-CoV-2 variants may boost enhancing antibodies more than the neutralizing antibodies in individuals who were previously infected with wild-type SARS-CoV-2 or immunized with vaccines composed of wild-type spike protein. Immunization using the RBD alone, which will not induce anti-NTD enhancing antibodies, could be a strategy for a vaccination. However, anti-NTD neutralizing antibodies that protect against SARS-CoV-2 infection similar to anti-RBD-neutralizing antibodies are not induced by immunization by RBD alone (Chi et al., 2020; Li et al., 2021 ; Liu et al., 2020; Suryadevara et al., 2021; Voss et al., 2021). Whole spike protein containing RBD mutations observed in major variants but lacking the enhancing antibody epitopes may need to be considered as a booster vaccine.

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Author contributions

Y.L., Y.M., D.M.S., T.K., M.O., M.F., H.A. designed the experiments. Y.L., J.K., M.H., A.T, S.M., A.A., K.A., C.O., H.J., K.K., W.N., performed the experiments. N.A., A.K., H.N., Y.Y., M.F. collected vaccine sera. J.K., S.L., D.M.S, T.K., H.A. constructed a model of NTD spike. Y.L., N.A., J.K, M.K., D.M.S, H.A. wrote the manuscript. All authors read, edited, and approved the manuscript.

Declaration of interests

Osaka University has filed a patent application for the enhancing antibodies. HA and YL are listed as inventors. HA is a stockholder of HuLA immune Inc.

Methods

Data and code availability

Cryo-EM density maps for the SARS-CoV-2 Delta spike protein were deposited at the EMDB under accession code EMD-31731. A molecular model of the SARS-CoV-2 Delta spike protein fitted to Cryo-EM data were deposited to PDB under accession code 7V5W. The data that support the findings of this study are available from the Lead Contact on request.

Cell lines

HEK293T cells (RIKEN Cell Bank) and B16F10 melanoma cells (National Institute of Biomedical Innovation) were cultured in DMEM (Nacalai, Japan) supplemented with 10% FBS (Biological Industries, USA), penicillin (100 U/mL), and streptomycin (100 μg/mL) (Nacalai, Japan) and cultured at 37°C in 5% CO_2. The Expi293 cells (Thermo) were cultured with the Expi293 medium. The cells were routinely checked for mycoplasma contamination. ACE2-stably transfected HEK293 cells (HEK293T-ACE2-transfectants) were reported previously (Liu et al., 2021b).

Human samples

The collection and use of BNT162b2-immune sera were approved by Osaka University Hospital (20522-3). Written informed consent was obtained from the participants according to the relevant guidelines of the institutional review board. All sera were collected from 26-65 years old healthy individuals three weeks after immuniztion with two cycles of 30 μg of BNT162b2 mRNA vaccine.

Plasmid construction

The SARS-CoV-2 spike gene (NC_045512.2) was prepared by gene synthesis (IDT). The sequences encoding the spike protein lacking the C-terminal 19 amino acids (amino acids 1–1254) were cloned into the pME18S expression vector. NTD (amino acids 14–333) and RBD (amino acids 335–587) were separately cloned into a pME18S expression vector containing a SLAM signal sequence and a PILRα transmembrane domain (Saito et al., 2017). A series of mutants and the Delta variants (T19R, G142D, E156G, del_157, del_158, L452R, T478K, D614G, P681R, D950N)

were prepared from wild-type SARS-CoV-2 spike using the QuickChange Lighting Multi Site-directed Mutagenesis kit (Agilent). Additional RBD mutations were introduced into the Delta spike also using the QuickChange Lighting Multi Site-directed Mutagenesis kit (Agilent). The primers for mutagenesis were designed on Agilent's website (https://www.agilent.com/store/primerDesignProgram.jsp). For Cryo-EM analysis, the sequence encoding the spike protein's extracellular domain with a foldon and His-tag at the C-terminus (Cai et al., 2020) was cloned into a pcDNA3.4 expression vector containing the SLAM signal sequence. Also, mutations D614G, R686G R687S R689G, K986P, and V987P were introduced using a Quick change multi-mutagenesis kit (Agilent) for stabilization of recombinant spike protein (Yurkovetskiy et al., 2020). The DNA sequences of these constructs were confirmed by sequencing (ABI3130xl).

Transfection

A pME18S expression plasmid containing the full-length or subunit spike protein was transiently transfected into HEK293T cells using PEI max (Polysciences); the pMx-GFP expression plasmid was used as the marker of transfected cells.

Anti-spike monoclonal antibodies from COVID-19 patients

The variable regions of anti-SARS-CoV-2 spike antibodies from COVID-19 patients were synthesized according to the published sequence (IDT) (Brouwer et al., 2020; Chi et al., 2020; Li et al., 2021; Robbiani et al., 2020; Suryadevara et al., 2021; Zost et al., 2020). Variable region sequences of some antibodies were obtained from the CoV-AbDab database (http://opig.stats.ox.ac.uk/webapps/covabdab/). The cDNA of the variable regions of the heavy chain and light chain were cloned into a pCAGGS vector containing sequences that encode the human IgG1 or kappa constant region. The pCAGGS vectors containing sequences encoding the immunoglobulin heavy chain and light chain were co-transfected into Expi293 (Thermo) cells, and the cell culture supernatants were collected according to the manufacturer's protocols. Recombinant IgG was purified from the culture supernatants using protein A Sepharose (GE healthcare). The concentration of purified IgG was measured at OD280.

Antibodies and recombinant proteins

Allophycocyanin (APC)-conjugated donkey anti-mouse IgG Fc fragment antibody and APC-conjugated anti-human IgG Fc fragment specific antibody (Jackson ImmunoResearch, USA) were used. The pcDNA3.4 expression vector containing the sequence that encodes the His-tagged extracellular domain of the spike protein was transfected into Expi293 cells and the His-tagged spike protein produced in the culture supernatants was then purified with a Talon resin (Clontech).

Immunization of mice

B16F10 cells were transfected with WT spike protein or Delta spike protein by PEI as described above. 48 hours later, B16F10 cells were washed twice with PBS,and then the cells were collected and frozen and thawed. Balb/c female mice (7-weeks-old females) were purchased from SLC. Two groups of five mice (n = 5) were subcutaneously immunized with $1x10^7$ B16F10 transfectants in the presence of complete Freund's adjuvant (CFA). Serum samples were collected three weeks after the immunization.

Flow cytometric analysis of antibodies

Plasmids expressing the full-length SARS-CoV-2 spike protein, Flag-NTD-PILR-TM and Flag-RBD-PILR-TM were co-transfected with the GFP vector into HEK293T cells. The transfectants were incubated with the mAbs, followed by APC-conjugated anti-human IgG Ab. The antibodies

bound to the stained cells were then analyzed using a flow cytometer (Attune™, Thermo; FACSCelesta BD bioscience). Antibodies binding to the GFP-positive cells were shown in the figures using FlowJo software (BD bioscience).

SARS-CoV-2 spike-pseudotyped virus infection assay

The HEK293T cells were transiently transfected with expression plasmids for the SARS-CoV-2 spike protein lacking the C-terminal 19 amino acids (Hu et al., 2020; Johnson et al., 2020). At 24 hours post-transfection, VSV-G-deficient VSV carrying a Luciferase gene complemented in *trans* with the VSV-G protein was added for incubation for 2 hours. The cells were then carefully washed with DMEM media without FBS and incubated with DMEM with FBS at 37°C in 5% CO_2 for 48 hours. The supernatant containing the pseudotyped SARS-CoV-2 virions was harvested and aliquoted before storage at −80°C. To determine the virus titers of the pseudovirus, 1×10^4 HEK293T-ACE2-transfectants were mixed with the pseudovirus for 20 hours at 37 °C in 5% CO_2 in a 384-well plate (Greiner, Germany). Luciferase activity was measured using a ONE-Glo™ luciferase assay (Promega, USA) according to the manufacturer's instructions. The signals were measured by a luminescence plate reader (TriStar LB94, Berthold Technologies, Germany) **(Figure S1)**. For the neutralization assay, 5 µl pseudovirus was mixed with equal volume of sera or monoclonal antibodies at the concentrations indicated in the figure. The mixture was added to 20 µl of 1×10^4 HEK293T-ACE2-transfectants. To calculate % neutralization, the relative luminescence units of the virus control wells (pseudovirus only) were subtracted from those of the sample wells, and the subtaracted values were divided by those of the virus control wells. The PRNT50 neutralization titers for vaccinated sera were determined using 3-parameter nonlinear regression curve (GraphPad Prism). If the PRNT50 titer was less than 1:10, it was defined as 0.

Structure prediction by AlphaFold2

The NTD and RBD structures of the wild type and Delta variant were predicted by AlphaFold2 (Jumper et al., 2021). The structure of the NTD was predicted in CASP14 mode without template. The structure of the RBD was predicted in CASP14 mode, using the template of 2020-05-14. The highest ranked prediction results were used.

Cryo-EM data collection

A 2.5 µl protein solution of the spike protein (2.2 mg/ml) was applied onto the cryo-grid and frozen in liquid ethane using a Vitrobot IV (Thermo Fisher Scientific, USA, 4°C and 100% humidity). Quantifoil Au R0.6/1.0 holey carbon grids were used for the grid preparation. Data collection of the sample was carried out on a Titan Krios (Thermo Fisher Scientific, USA) equipped with a thermal field emission electron gun operated at 300 kV, an energy filter with a 20 eV slit width and a bioquantum K3 direct electron detection camera (Gatan, USA) (Figure S4). For automated data acquisition, SerialEM software was used to collect cryo-EM image data. Movie frames were recorded using the K3 camera at a calibrated magnification of × 81,000 corresponding to a pixel size of 0.88 Å with a setting defocus range from −0.8 to −2.0 µm. The data were collected with a total exposure of 3 s fractionated into 62 frames, with a total dose of ~ 60 electrons $Å^2$ in counting mode. A total number of movies were collected; 15,000 for the spike protein.

Image processing and 3D reconstruction

All of image processes were carried out on cryoSPARC software (Punjani et al., 2017). After motion correction of movies and CTF parameter estimation, the particles were automatically picked using Topaz software (Bepler et al., 2019). The detailed information is summarized in Table S1. The picked particles were extracted into a box of 360 × 360 pixels. After particle extraction, the particles were applied to two rounds of heterogenous refinement with C1 symmetry. The

selected particles (735,623 particles) were applied to two rounds of *ab-initio* reconstruction into three classes with C1 symmetry. In the first and second rounds of ab-initio reconstruction, the class similarity parameter, 0.1 and 0.8, was used, respectively. After that, the selected 147,497 particles were further used as non-uniform refinement with optimizing per-particle defocus. As the result, the density map for the spike protein was obtained at 3.16 Å resolution. Local resolution of the obtained maps were estimated by Local resolution estimation job on cryoSPARC.

Model building and refinement

To generate the atomic model for the spike protein, the structure of NTD of Delta variant was predicted using AlphaFold2 (Jumper et al., 2021). For other domains, the model from previous study (PDBID; 7JJI) was used. These structures were fitted into the density map as rigid body using UCSF chimera (Pettersen et al., 2004). The initial model was extensively manually corrected residue by residue in COOT (Emsley et al., 2010) in terms of especially side-chain conformations. The corrected model was refined by the phenix.real_space_refine program (Liebschner et al., 2019) with secondary structure and Ramachandran restraints, then the resulting model was manually checked by COOT. This iterative process was performed for several rounds to correct remaining errors until the model was in good agreement with geometry, as reflected by the MolProbity score of 2.07 (Williams et al., 2018). For model validation against over-fitting, the built models were used for calculation of FSC curves against the final density map used for model building by phenix.refine program. The statistics of the obtained maps and the atomic model were summarized in Supplemental Table S1.

Data and statistical analysis

FlowJo version 10.7 (BD Biosciences, USA) was used to analyze the flow cytometry data, and Graphpad Prism version 7.0e was used for graph generation and statistical analysis.

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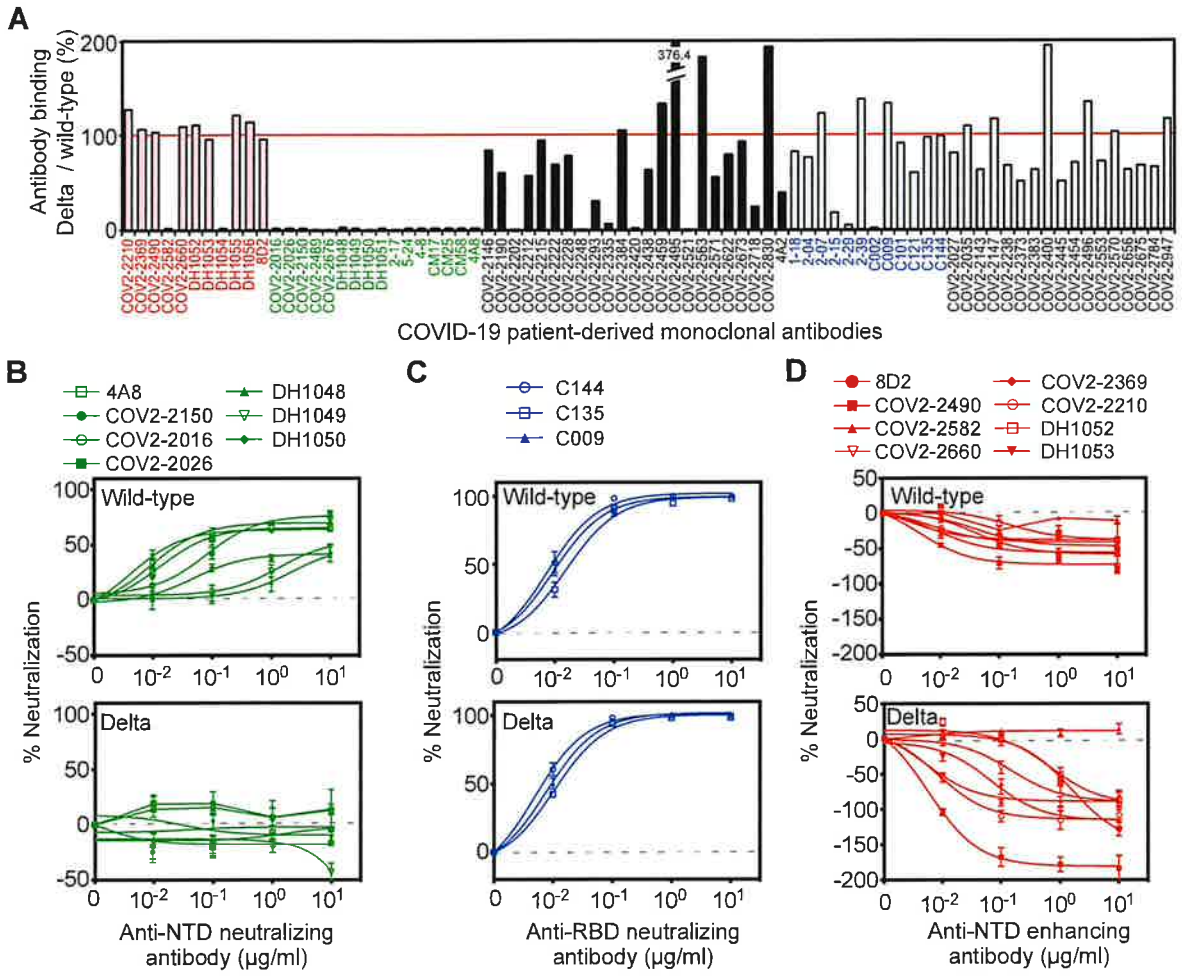


Figure 1. Neutralizing and enhancing effects against the wild-type and Delta spike pseudovirus by anti-spike monoclonal antibodies from COVID-19-patients.

(A) The HEK293 cells transfected with the wild-type or the Delta spike were stained with anti-NTD enhancing antibodies (red), anti-NTD neutralizing antibodies (green), anti-NTD non-enhancing, non-neutralizing antibodies (black), anti-RBD neutralizing antibodies (blue) and anti-S2 antibodies (gray) (1 μg/ml). The stained cells were analyzed by flow cytometer. The relative mean fluorescence intensities (MFI) of antibodies binding to the Delta spike were compared with that for the wild-type spike.

(B-D) The ACE2-expressing HEK293 cells were infected with the wild-type (upper) or the Delta (lower) pseudovirus in the presence of the anti-NTD neutralizing antibodies (B), anti-RBD neutralizing antibodies (C) and anti-NTD enhancing antibodies (D). A negative value for % neutralization indicates enhanced infectivity. The data from quadruplicates are presented as mean ± SEM. The representative data from three independent experiments are shown. See also Figure S1.

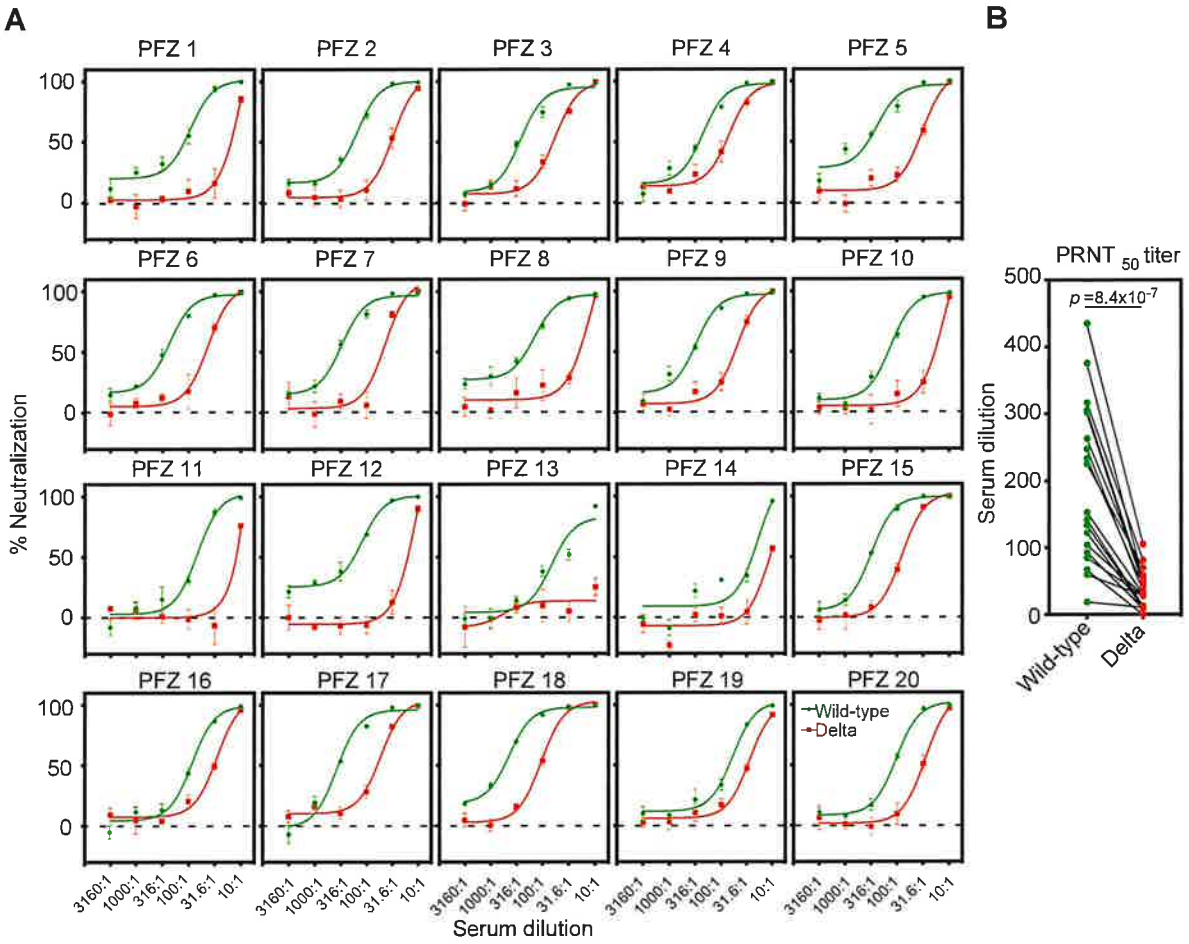


Figure 2. Neutralizing activity of BNT162b2-immune sera against the wild-type and the Delta pseudovirus.

(A) Neutralizing activity of twenty BNT162b2-immune sera against the wild-type (green) and the Delta (red) pseudovirus. Data are mean ± SEM of technical quadruplicates.

(B) PRNT50 titers of the BNT162b2-immune sera against the wild-type (green) and the Delta (red) pseudovirus are shown. *p* values determined by paired t-test were indicated. The representative data from three independent experiments are shown. See also Figure S1.

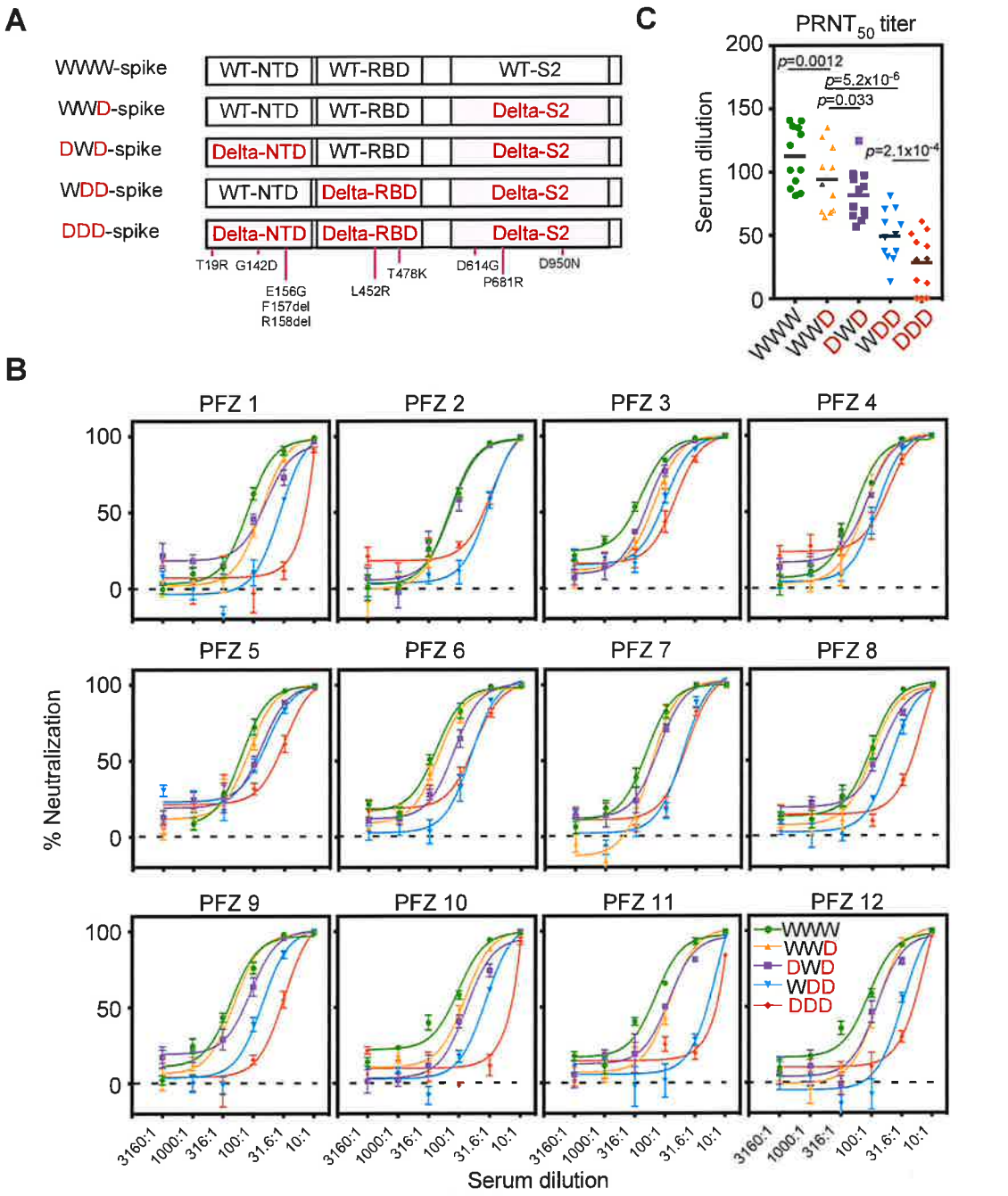


Figure 3. Neutralizing activity of BNT162b2-immune sera against the pseudovirus with chimeric spike protein of the wild-type and Delta variants.

(A) The chimeric spike proteins between the wild-type (W) and Delta variant (D). Mutations of the Delta spike are indicated.

(B) Neutralizing activity of BNT162b2-immune sera against the pseudoviruses with chimeric spike proteins. The data from quadruplicates are presented as mean ± SEM.

(C) PRNT50 titers of BNT162b2-immune sera against the pseudoviruses with chimeric spike proteins. *p* values determined by paired t-test were indicated. The representative data from 2 independent experiments are shown. See also Figure S1 and S2.

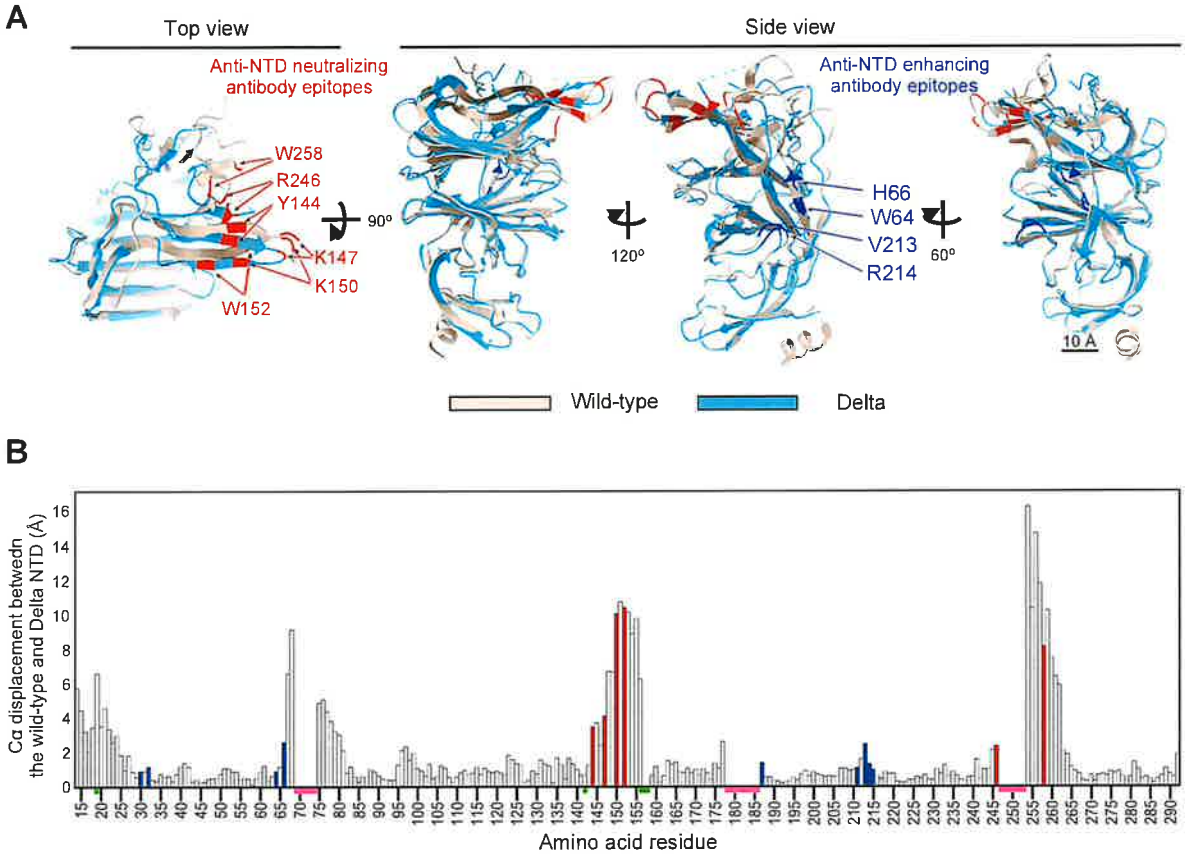
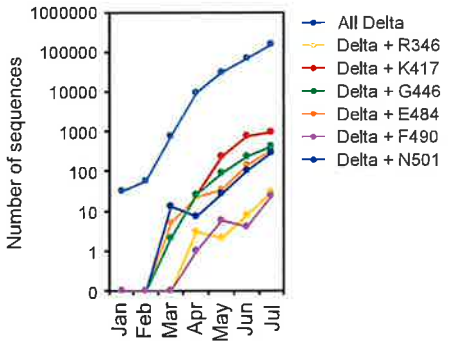


Figure 4. Cryo-EM analysis of the Delta NTD

(A) Structure of the Delta NTD (light blue) analyzed by the Cryo-EM were superimposed with the wild-type NTD (light brown, PDB: 7LY3). Major anti-NTD enhancing antibody epitopes (blue) and anti-NTD neutralizing antibody epitopes (red) were indicated in the figure.

(B) Cα displacement between the wild-type and the Delta NTD was shown. The value was calculated by UCSF chimera. All known anti-NTD enhancing antibody epitopes (blue) and anti-NTD neutralizing antibody epitopes (red) were indicated. The regions where structures of wild-type or Delta NTD were not determined (magenta), and mutations in the Delta NTD (green) are indicated on the axis. See also Figure S3 and Table S1.

A



C

Rank	Replacement	Number of sequences
1	N501Y	257,333
2	S477N	36,814
3	L452R	22,334
4	N439K	21,141
5	E484K	16,426
6	K417N	6,595
7	T478K	6,559
8	S494P	2,862
9	A520S	2,409
10	N501T	2,167
11	K417T	1,616
12	V367F	1100

B

The Delta variants with multiple mutations at the RBD

Additional mutations	Accession No.	Mutations at anti-RBD neutralizing antibody epitopes				
2	EPI_ISL_3032383	K417N	L452R	T478K		N501Y
2	EPI_ISL_3032382	K417N	L452R	T478K		N501Y
2	EPI_ISL_2694907	K417N	L452R	T478K		N501Y
2	EPI_ISL_2645948	K417N	L452R	T478K		N501Y
2	EPI_ISL_2958468		L452R	T478K	E484K	N501Y
2	EPI_ISL_3032707		L452R	T478K	E484K	N501Y
2	EPI_ISL_3138645		L452R	T478K	F490L	N501Y
2	EPI_ISL_3185883		G446V	L452R T478K	E484Q	
2	EPI_ISL_3301206		G446V	L452R T478K	E484Q	
2	EPI_ISL_3032702		G446S	L452R T478K		N501Y
2	EPI_ISL_3306497		G446S	L452R T478K		N501Y
2	EPI_ISL_3064582	R346K		L452R T478K	E484K	
3	EPI_ISL_2958474			L452R T478K	E484K F490S	N501Y
4	**Delta 4+**	**K417N N439K**		**L452R T478K**	**E484K**	**N501Y**

D

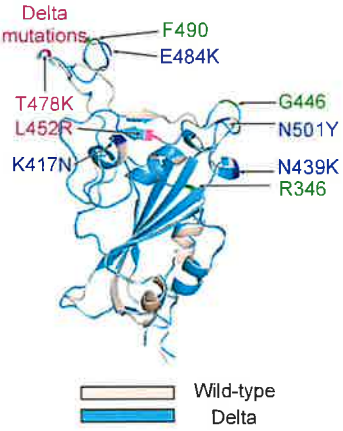


Figure 5. Possible mutations that may be acquired by the Delta variant

(A) Number of the Delta variants with additional mutations at the RBD registered in the GISAID database in each month from January, 2021 to July, 2021. The data registered at July are not enough and will be increased later.

(B) The Delta variants with additional mutations at multiple epitopes of the anti-RBD neutralizing antibodies. L452R and T478K mutations are observed in all the Delta variants (purple). Anti-RBD neutralizing antibody epitopes introduced into the Delta 4+ (blue), and anti-RBD neutralizing antibody epitopes observed in the natural Delta variants but not introduced into the Delta 4+ (green) are shown with the respective GISAID accession number.

(C) Number of the major RBD mutations acquired by all SARS-CoV-2 variants. L452R and T478 are mutations observed for the representative Delta variant (blue). N501Y, N439K, E484K and K417N were selected to generate the Delta 4+ variant (red).

(D) Location of additional mutations introduced into the Delta RBD. Structures of the RBD of the wild-type (light brown) and the Delta variant (light blue) predicted by AlphaFold2 were superimposed. Mutations of the Delta variant (purple), anti-RBD neutralizing antibody epitopes to generate the Delta 4+ (blue), and anti-RBD neutralizing antibody epitopes observed in the natural Delta variants but not introduced into the Delta 4+ (shown in C; green) are indicated in the figure. See also Figure S4.

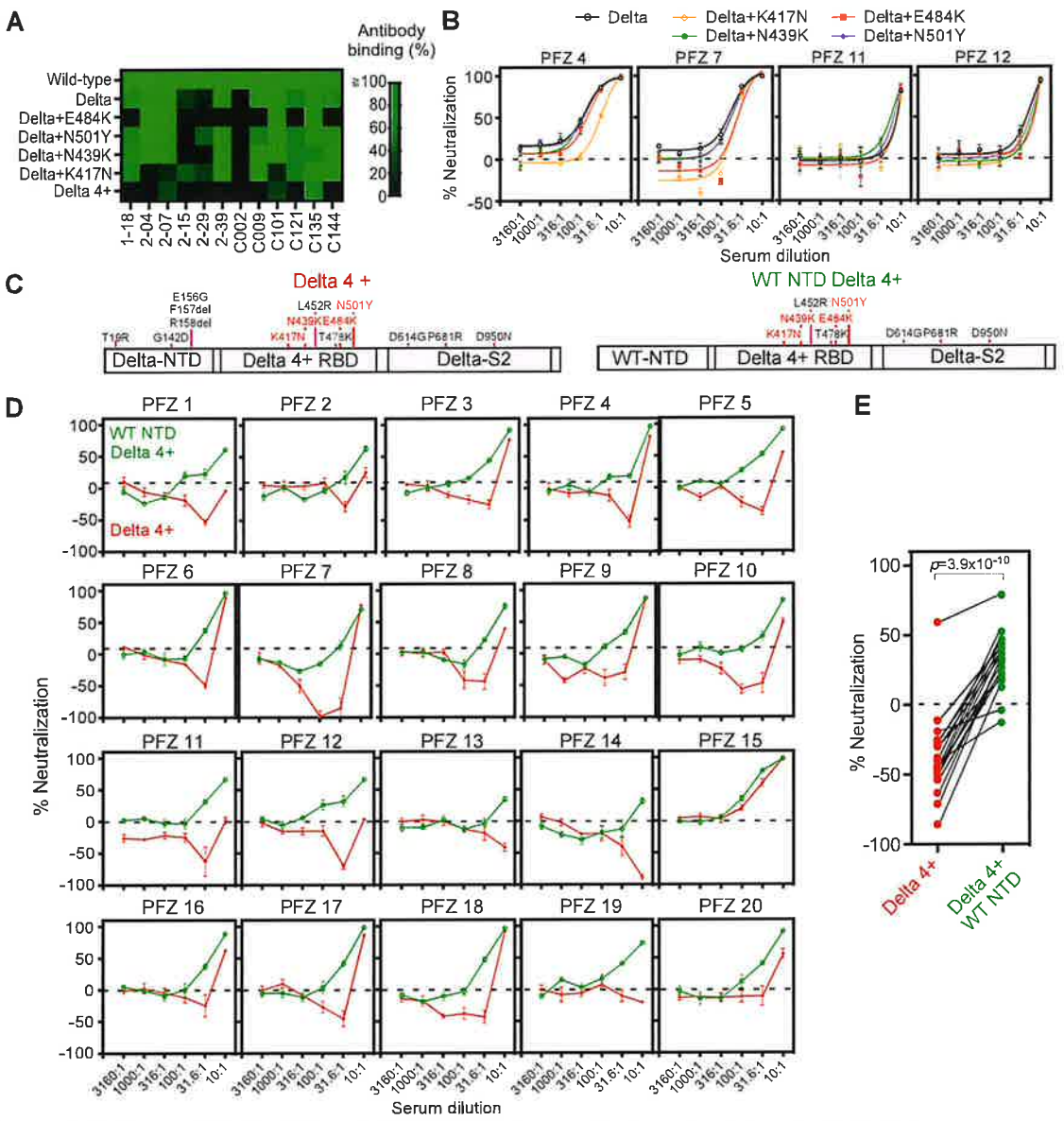


Figure 6. Enhanced infectivity of the Delta 4+ pseudovirus by the BNT162b2-immune sera

(A) Anti-RBD antibody binding to the Delta spike with additional mutations at the RBD. Anti-RBD mAb binding (1 μg/ml) to the mutant spike was compared to that of the wild-type spike. The Delta 4+ spike contains additional mutations of K417N, N439K, E484K and N501Y.

(B) Neutralizing activity of BNT162b2-immune sera against the Delta pseudoviruses with a single additional mutation at the RBD as indicated in the figure. The data from quadruplicates are presented as mean ± SEM.

(C) The construct of the Delta 4+ and Delta 4+ with wild-type (WT) NTD. Mutations in the original Delta variant (black) and the four mutations added to the Delta RBD (red) were shown.

(D) Neutralizing activity of BNT162b2-immune sera against the pseudovirus with Delta 4+ spike (red) and Delta 4+ spike with wild-type NTD (green).

(E) Neutralizing activity of 31.6 times diluted BNT162b2-immune sera. *p* value determined by paired t-test were indicated. Negative values for % neutralization indicates enhanced infectivity (B, D, E). The data from quadruplicates are presented as mean ± SEM. The representative data from three independent experiments are shown.

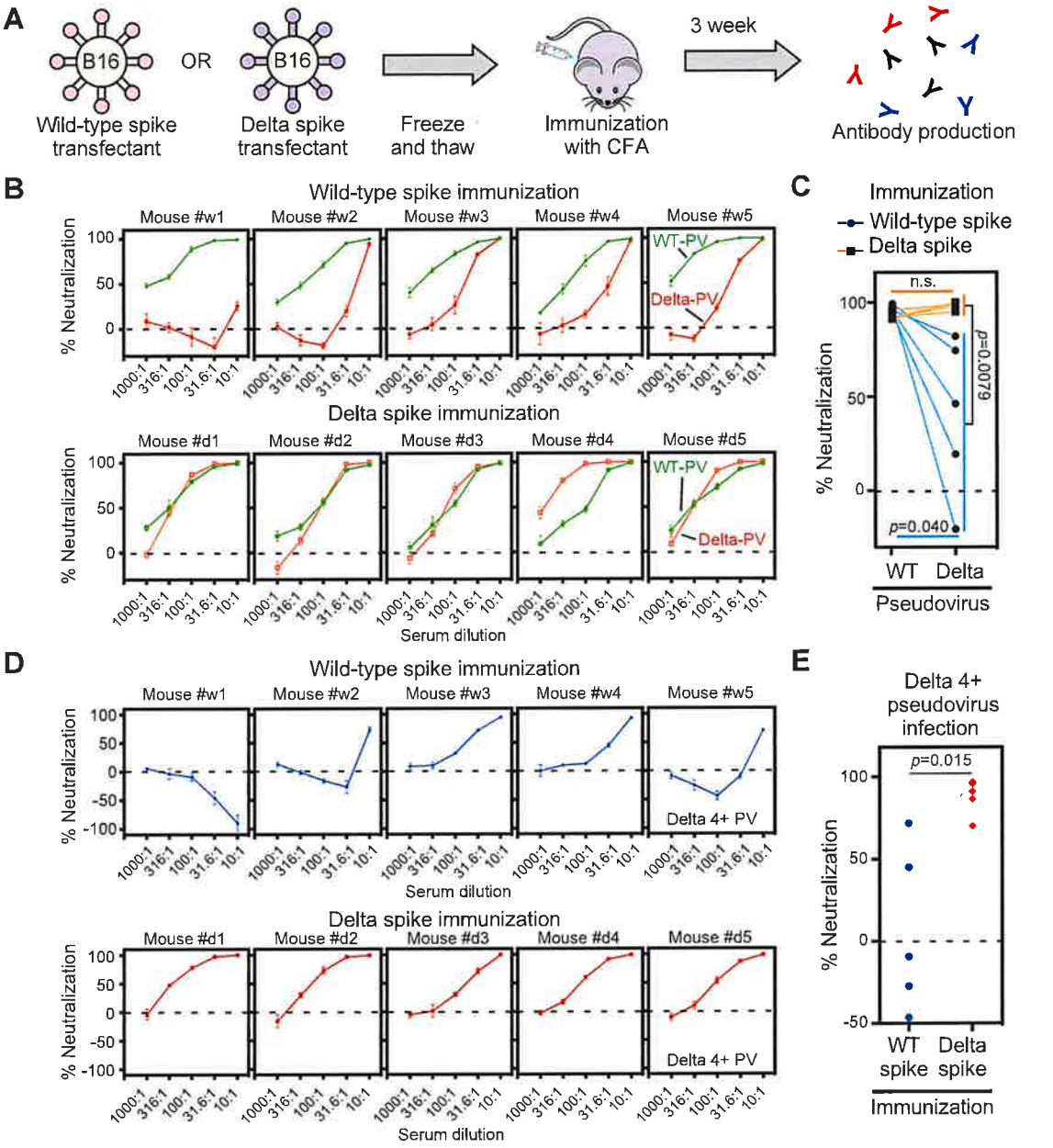


Figure 7. Sera from delta spike-immunized mice do not show enhanced infectivity

(A) Freeze and thawed wild-type and Delta spike-B16 transfectants were immunized to the mice with complete Freund's adjuvant (CFA).

(B) Neutralizing activity against the wild-type (green) or Delta (red) pseudovirus (PV) by sera from the wild-type spike (upper column) or Delta spike (lower column) spike-immunized mice.

(C) Neutralizing activity against the wild-type and Delta pseudovirus by 31.6 times-diluted sera from wild-type (light blue line) or Delta (orange line) spike-immunized mice.

(D) Neutralizing activity against the Delta 4+ pseudovirus by sera from the wild-type spike (upper column, blue) or Delta spike (lower column, red) immunized mice.

(E) Neutralizing activity against the Delta 4+ pseudovirus by the 31.6 times-diluted sera from the wild-type spike (blue) or Delta spike (red) immunized mice. n.s.: not statistical significance, *p* value was determined by t-test. A negative values for % neutralization indicates enhanced infectivity. All data from quadruplicates are presented as mean ± SEM. See also Figure S1 and S5.

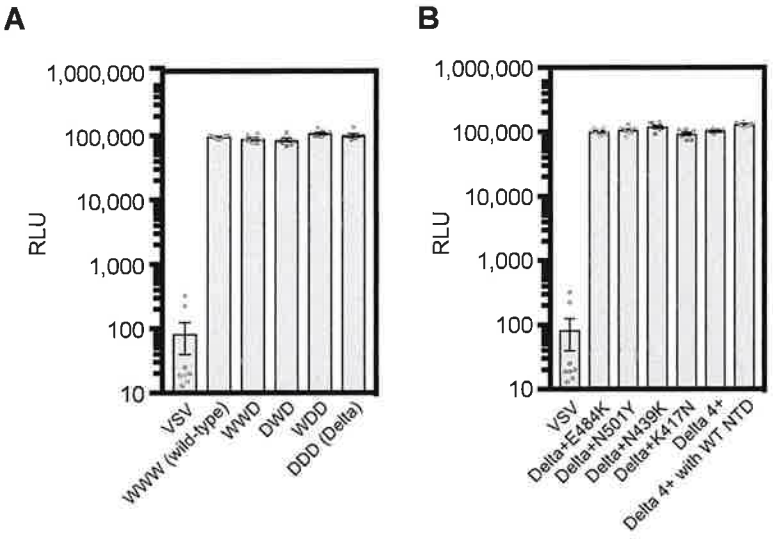


Figure S1. Viral titers of pseudotyped viruses, related to Figure 1, 2, 3, 6 and 7.
The viral titer for each psudoviruses was measured by infection of ACE2-transfected HEK293T cells as described in Methods.

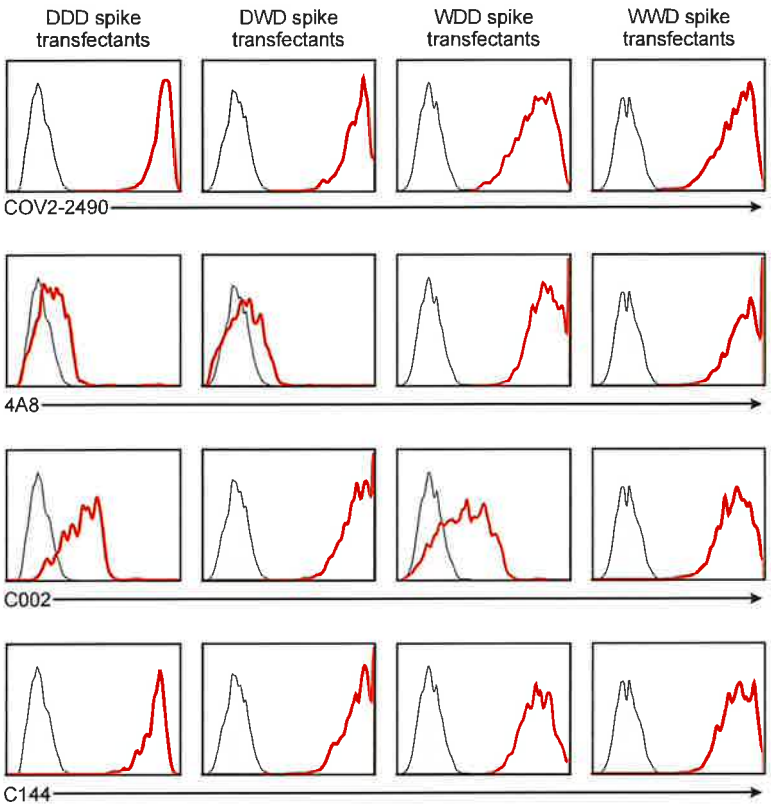


Figure S2 Anti-spike monoclonal antibody binding to the chimeric spike proteins, related to Figure 3.

Chimeric spike proteins DDD, DWD, WDD and WWD were transfected with GFP to HEK293T cells and the transfectants were stained with 1 μg/ml COV2-2490, 4A8, C002, and C144 antibodies. Antibody bound to the GFP positive cells are shown (red histogram). Control staining: shaded histogram.

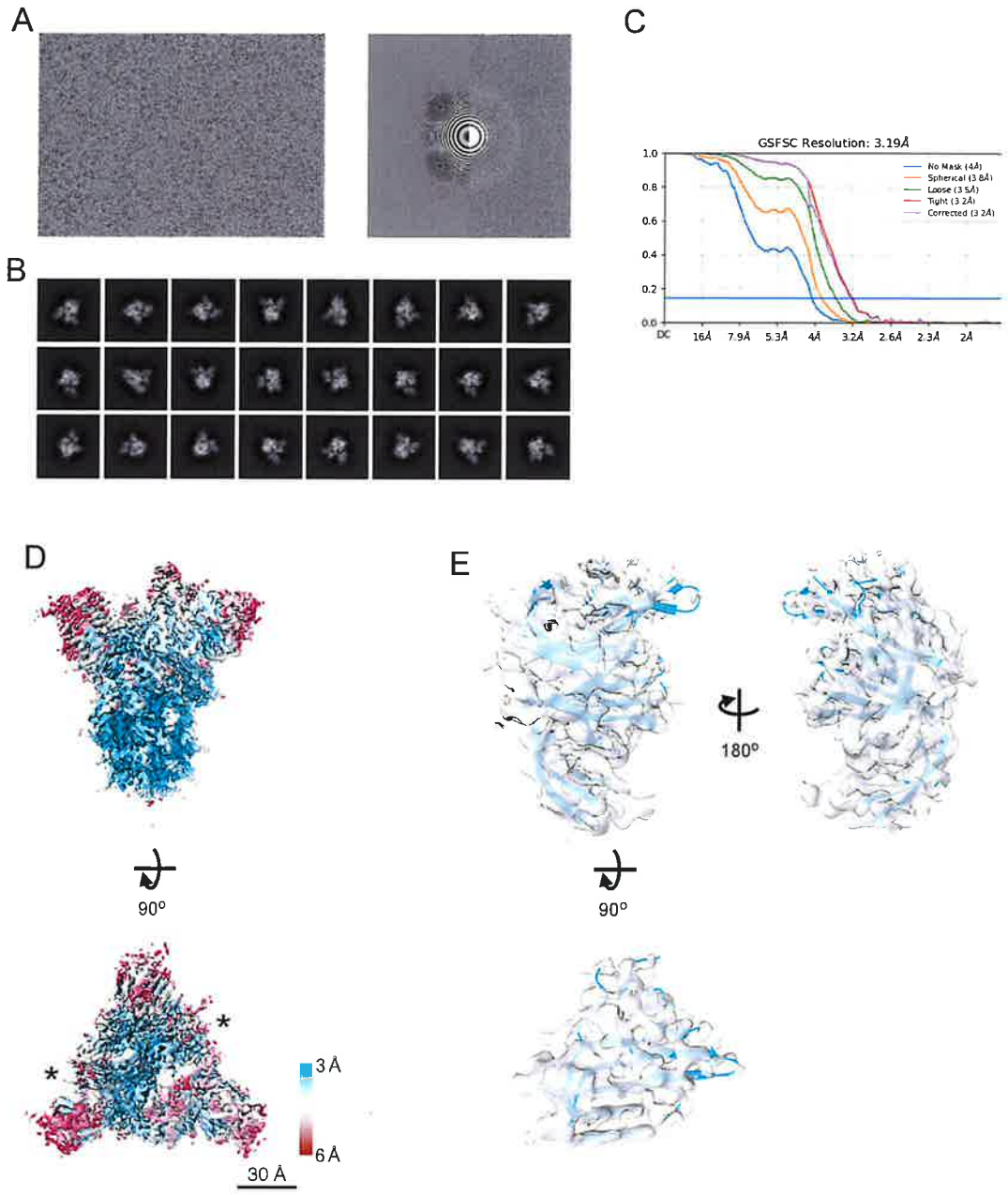


Figure S3. Cryo-EM density map of spike of SARS-CoV-2 Delta variant, related to Figure 4.
(A) A representative micrographs (left), CTF estimation of a micrograph on left panel (right).
(B) Typical 2D class averages.
(C) The GS-FSC curves for the obtained map from cryoSPARC software are shown. Blue flat line indicates FSC=0.143 criteria.
(D) The density map of spike protein from Delta strain (EMDBID: 31731). The map is colored with local resolution. Asterisks indicate the up form of RBDs. Scale bars are 30 Å.
(E) The structure of NTD from spike protein of Delta variant. The density map and the model are shown as semi-transparent surface and cartoon, respectively (PDBID: 7V5W).

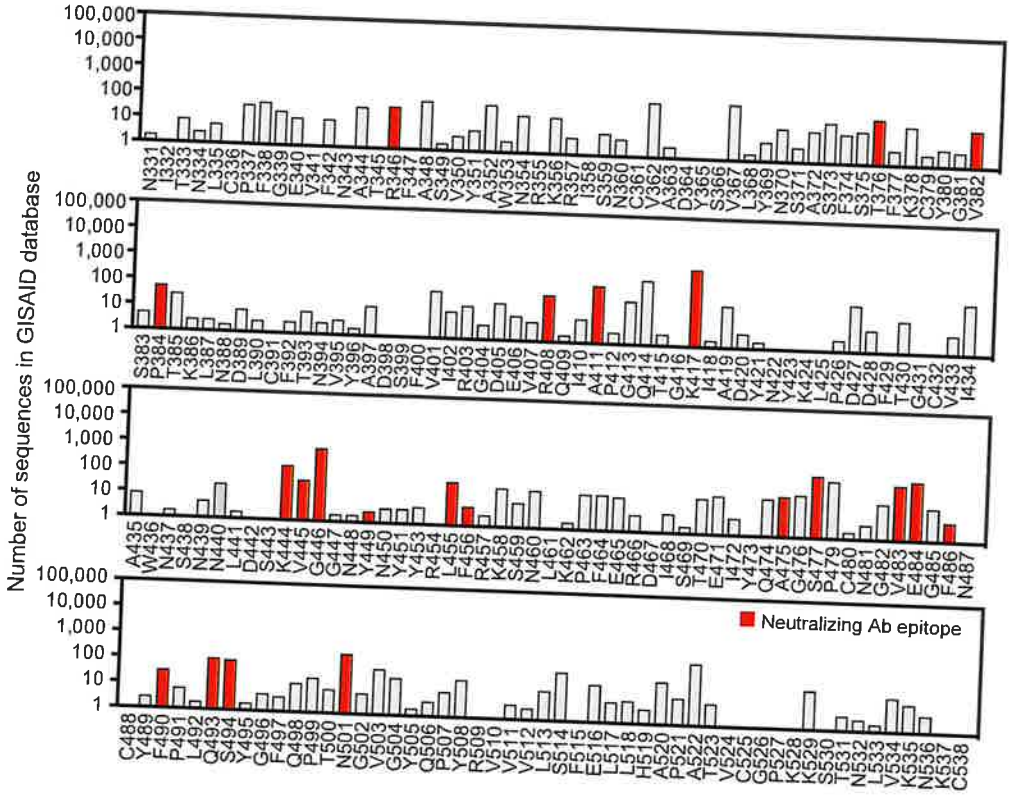


Figure S4. RBD mutations acquired by the Delta variant, related to Figure 5.

Number of RBD mutations acquired by the Delta variant. The numbers of mutations at each residue registered in the GISAID database are shown. L452 and T478 mutations included in all the Delta variant were excluded. The red bars indicate the known epitopes for anti-RBD neutralizing antibodies.

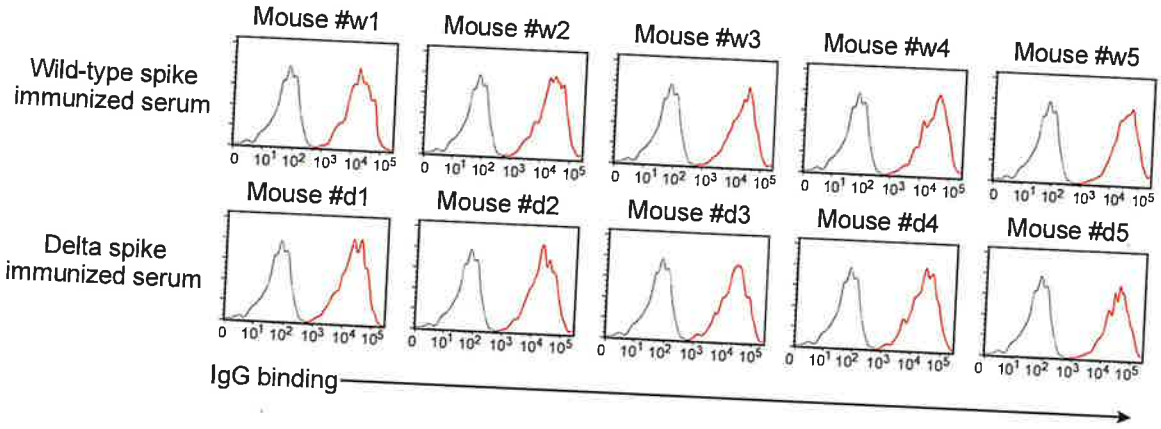


Figure S5 Anti-spike antibodies of the wild-type and delta spike-immunized mice, related to Figure 7.

IgG antibody binding of the 100 times diluted spike-immunized mouse sera to the wild-type spike transfectants were analyzed by flow cytometer. Red: IgG binding. Gray: Control staining.

Table S1. Cryo-EM data collection and processing statistics, related to Figure 4.

Data collection		
Sample		Spike protein of SARS-CoV2 Delta strain
Micorscope		Titan Krios
Acc. Voltage (kV)		300
Total electron dose (e^-/Å)		50
Pixel size (Å)		0.88
Defocus range (μm)		-0.8 – -2.0 (0.15)
Magnification		81,000
Corrected Cs (mm)		0.064
Data processing		
Software		CryoSparc v3.2.0
# of Micrographs		15,000
# of particles		147,497
Symmetry		C1
Resolution (Å, GS-FSC=0.143)		3.19
EMDB ID		31731
Model building		
Method		Rigid body fitting & Coot
Template model		AlphaFold2 prediction, 7JJI, 7N01
# of Atoms		21,634 (2,725 residues)
modification		NAG: 27
MolProbity score		2.07
Map vs model resolution (FSC = 0.5)		3.3 (masked)
Ramachandran (%)	Favored	90.54
	Allowed	9.16
	Outlier	0.30
Clash score		10.42
CaBLAM outeliers (%)		4.15
RMSZ bound length (Å)		0.006
RMSZ bound angle (°)		0.814
PDBID		7V5W

EXHIBIT 4

St. Elizabeth PHYSICIANS | St. Elizabeth HEALTHCARE

Employee Health
375 Thomas More Pkwy, Ste 205
Crestview Hills, KY 41017
Phone: (859) 301-6265
Fax: (859) 301-5462

COVID Vaccine Medical Exemption Statement

Associate Name: _____ Date of Birth: _____ Employee ID: _____

Associate Address: _____
(Street) (City) (State) (Zip Code)

Job Information: _____
(Job Title) (Department) (Location)

MEDICAL PROVIDER COMPLETES THIS SECTION

A licensed physician, physician assistant, nurse practitioner or licensed midwife must complete this medical exemption statement and provide their information below:

Select the reason(s) for exemption:

- ☐ A documented history of severe or immediate-type allergic reaction to any ingredient of all currently available COVID-19 vaccine brands. (Vaccine ingredients for each of the vaccine brands is available at: https://www.cdc.gov/vaccines/covid-19/eua/index.html). List vaccine ingredient(s) the patient is allergic to: _____
- ☐ A documented history of severe allergy or immediate-type hypersensitivity reaction to a previous COVID-19 vaccination, and also a separate contraindication to all currently available COVID-19 vaccine brands. Details: _____
- ☐ For the J&J/Janssen vaccine: A history of a specific heparin allergy known as heparin-induced thrombocytopenia (HIT) may be a contraindication or reason to defer the vaccination. Details: _____
- ☐ Other - Medical condition that requires employee to not receive the vaccination. Details: _____

The following conditions are <u>not</u> considered medical contraindications to COVID-19 vaccination but for which a postponement of the vaccination to a later date may be approved:

- ☐ Pregnancy. Anticipated delivery date: _____
- ☐ Prior positive COVID-19 test: If an individual tests positive for COVID-19 prior to their first vaccine, they should wait four weeks before getting their first vaccine dose. If they test positive for COVID-19 after the first vaccine but prior to the second vaccine, they should wait 10 days from the positive test and be fully recovered and non-infectious before receiving the second dose. Details: _____

Note: The following conditions are <u>not</u> considered medical contraindications to COVID-19 vaccination:

- A history of allergy or anaphylaxis to foods, antibiotics, other oral medications, pets, venom, other environmental allergies, or non-COVID vaccines.
- A history of latex allergy (as there is no latex is in the vaccine or in the vial stopper).
- Individuals who do not eat eggs or gelatin (as neither of the currently available vaccines contain these)
- Family history of adverse vaccine reactions or autoimmune conditions.
- Fear of needles or general avoidance of vaccines.

Add any supporting data (please include any pertinent labs or studies, specialist notes, etc.)

Exemption is temporary and vaccination can be initiated at a future date: ☐Yes ☐No

Anticipated duration of temporary exemption: _____

Provider's Name (Print): _____

Office Address: _____ Office Phone: _____

Signature: _____ Date: _____

Do not mark in this box. For St Elizabeth Employee Health Only

Medical Exemption Status: ☐ Approved ☐ Declined Date: _____

Reason:

EXHIBIT 5

Provider Name	State	Provider Relief Fund	AAP	Total
ST ELIZABETH MEDICAL CENTER, INC	Kentucky	$67,360,199	$104,992,179	$172,352,378
BETHESDA HOSPITAL, INC. (TRIHEALTH)	Ohio	$107,129,964	$54,906,072	$162,036,036
UNIVERSITY OF CINCINNATI MEDICAL CENTER LLC	Ohio	$60,149,438	$99,135,673	$159,285,111
THE CHRIST HOSPITAL	Ohio	$42,549,094	$91,694,926	$134,244,020
THE GOOD SAMARITAN HOSPITAL OF CINCINNATI, OHIO (TRIHEALTH)	Ohio	$46,801,403	$51,877,170	$98,678,573
CHILDREN'S HOSPITAL MEDICAL CENTER	Ohio	$92,403,255	$0	$92,403,255
MERCY HEALTH - WEST HOSPITAL, LLC	Ohio	$22,316,441	$26,338,185	$48,654,626
MERCY HEALTH-FAIRFIELD HOSPITAL LLC	Ohio	$17,355,285	$13,616,179	$30,971,464
MERCY HEALTH - ANDERSON HOSPITAL, LLC	Ohio	$4,899,703	$22,566,390	$27,466,093
ST ELIZABETH FT THOMAS (High Impact Covid Fund)	Kentucky			$15,650,000
MERCY HEALTH-CLERMONT HOSPITAL, LLC	Ohio	$2,423,220	$12,527,438	$14,950,658
UNIVERSITY OF CINCINNATI PHYSICIANS COMPANY LLC	Ohio	$3,339,037	$9,947,769	$13,286,806
MERCY HEALTH PHYSICIANS CINCINNATI LLC	Ohio	$3,425,578	$8,256,207	$11,681,785
TRIHEALTH PHYSICIAN ENTERPRISE CORP.	Ohio	$9,153,780	$0	$9,153,780
MERCY HEALTH - WEST HOSPITAL (High Impact Covid Fund)	Ohio			$8,600,000
TRIHEALTH G LLC	Ohio	$7,749,513	$0	$7,749,513
TRIHEALTH HOSPITAL, INC.	Ohio	$6,794,762	$0	$6,794,762
MERCY HEALTH PHYSICIANS KENTUCKY LLC	Kentucky	$888,797	$2,146,668	$3,035,465
ST. ELIZABETH HOME CARE SERVICES LLC	Kentucky	$506,928	$1,944,055	$2,450,983
CHRIST HOSPITAL MEDICAL SPECIALISTS II, LLC	Ohio	$1,969,935	$0	$1,969,935
BETHESDA HEALTH AND REHAB CENTER, INC.	Ohio	$434,630	$0	$434,630
BETHESDA MRI LLC	Ohio	$95,933	$233,459	$329,392
	Totals	$457,796,699	$500,182,370	$1,012,179,269

EXHIBIT 6

AFFIDAVIT

State of Ohio

County of Clermont

I, Jamie Kendrick Waselenko, MD, of 1773 Clough Pike, Batavia, OH 45103, after being duly sworn in I do hereby swear under oath that:

1. Based on a reasonable degree of medical certainty, I believe the current COVID 19 mRNA gene-based therapies are unsafe and pose a serious long-term risk to those that are vaccinated. The data and evidence that substantiate this position are as follows:

A. Firstly, one must understand that everything we do and offer in medicine is based on a risk and benefit analysis. The benefit of any therapy must exceed the risk of side effects. In other words, the treatment and its toxicities should not be worse than the disease. Herein, COVID-19 will be used synonymously with severe acute respiratory coronavirus 2 (SARS-CoV-2), the causative agent of COVID-19. While COVID-19 is highly contagious, the risk of COVID-19 induced serious illness in most of the populations is very low, especially in those that are less than 64 years of age; refer to Table 1. Note that in tables 1 and 2, children, adolescents, and young adults, as well as those under the age of 50 have an extremely low mortality, which approaches 0 in children and young adults. This mortality approaches the annual mortality of influenza, a different seasonal respiratory virus, that has not yielded the recent draconian measures. Based on this data, the current mass vaccination for this population is inappropriate, especially given the unknown long-term effects of this genetic based therapy never before used in humans. I am not alone in this opinion. Many scientists and physicians in the US and Europe have been speaking out about the medical risks and concerns. Unfortunately, they are being silenced by the unprecedented uniform censorship occurring across the globe.

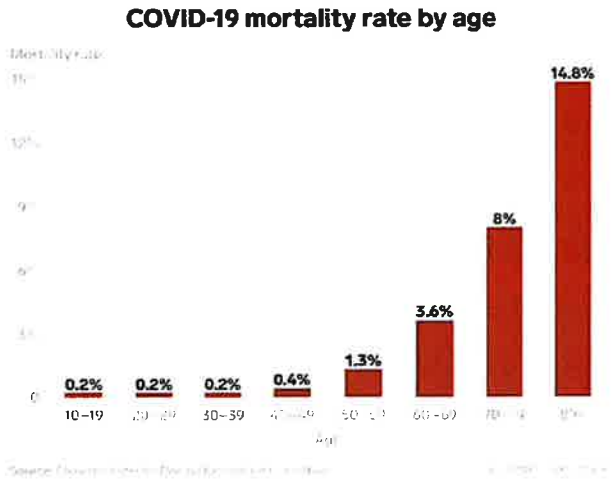
Table 1. Risk of death of COVID-19 based on age.

CA Covid-19 Data by Age Group (July 6, 2020)

Age	Population	Cases	% Cases	Deaths	Deaths/Case
0-17	8,890,250	22,861	0.26% (1 in 389)	0	00.0% (1 in NA)
18-49	17,187,817	162,714	0.95% (1 in 106)	392	00.2% (1 in 415)
50-64	7,270,249	55,931	0.77% (1 in 130)	1,053	01.9% (1 in 53)
65+	6,163,907	35,957	0.58% (1 in 171)	4,916	13.7% (1 in 7)
Unknown	0	311	NA	1	00.3% (1 in 311)
Overall	39,512,223	277,774	0.70% (1 in 142)	6,362	02.3% (1 in 44)

Source: https://data.ca.gov/dataset/covid-19-cases

Table 2. This table depicts a low mortality, especially in those <60 years of age as reported by the Chinese Center for Disease Control and Prevention.



To re-affirm, mass vaccination of a low-risk population with a long-life expectancy is unnecessary and carries the risk of significant long-term harms. The risks do not outweigh the benefits; thus, this would be inappropriate. Offering vaccination to older patients (> 60 year of age), as the mortality starts to increase, with appropriate informed consent, realizing the experimental nature of the COVID-19 vaccines is plausible. However, informed consent requires you offer no treatment and discuss alternative therapeutic options for COVID-19 prophylaxis and treatment which do exist; see section 1. Subsection R. Unfortunately, these options have been suppressed and heavily politicized. Some of these medications, discussed later, have been used in thousands of patients and carry with them years of safety data. Dr. Vladimir Zelenko, MD, an expert in the management of COVID-19 with hydroxychloroquine, Zinc, and azithromycin, has argued that suppression of these data has cost thousands of lives.

B. The COVID-19 gene-based vaccines, are not vaccines. Vaccines typically use antigens, a suspension of weakened, killed, or fragmented microorganism or toxins, something that the body detects as foreign to induce an immune response. To meet the criteria to be considered a vaccine, the vaccine must:
Provide immunity to the virus itself, reduce death from the virus, reduce circulation of the virus and reduce transmission of the virus. The COVID-19 based gene therapies do none of these. They neither prevent the disease nor the transmission of the disease. Demanding a person who opts not to take the COVID-19 gene therapy to take it to protect others, demonstrates a complete lack of knowledge as it pertains to the science. The mRNA-based vaccines cause normal human cells to express an abnormal COVID-19 spike protein. Then, our cells must mount an immunologic attack on the normal cell, now expressing the spike protein. Immunologic diseases are always a potential with vaccines. This concern is heightened based on the normal cells now harboring the spike protein, which is now known to be the pathogenic portion of the COVID-19 virus. There is simply no long-term safety data in animals or humans.

C. To trust the science requires that we look at the science. The rapidity in which these gene therapies were pushed into humans is unprecedented. Typically, multiple animal studies are performed to look for evidence of a therapeutic benefit, as well as acute and long-term toxicity. Additional studies are done in animal models to explore evidence of fetal or gonadal toxicity which could lead to risk of birth defects, genetic damage, or long-term infertility. None of these have been performed or reported with the COVID-19 gene therapies. Even more concerning, all previous animal studies performed, employing coronavirus vaccines, showed more animals died in the vaccinated group as opposed to the unvaccinated. This was related to a process called pathogenic priming which yielded antibody dependent enhancement (ADE) or a hyper-immune activation which resulted in great harm and death to some of the animals due to overwhelming immune activation. These earlier animal trials employed experimental coronavirus vaccination candidates including the Middle East Respiratory Virus, SARS CoV1, and Respiratory Syncytial Virus which led to a successful antibody response in the animals, but further examination of these vaccines were all aborted due to an increase in deaths in the vaccinated animals once they were exposed to the actual virus. This resulted in abandonment vaccination exploration until now. The pharmaceutical companies bypassed the animal trials for the COVID-19 based-gene therapy candidates and went directly into humans, under the emergency use authorization, effectively making humans the test animals. I believe that we are starting to see antibody dependent enhancement in humans. There are reports all over the globe, showing an increased number of vaccinated patients admitted or in the intensive care unit, with COVID-19 compared to the unvaccinated. ADE would be expected to develop after exposure to a respiratory virus. Of note, the statistics in the US seem to be completely inverted as to what the rest of the world is seeing. Interestingly, some of the most heavily vaccinated countries have become COVID-19 hot spots and travel into these heavily vaccinated areas is limited due to the uptick in new cases. My concern is that this rush to get a vaccine into humans, was accomplished by bypassing necessary and critically important animal trials, which should give everyone pause. We will see unexpected side effects. The current mandates are criminal.

D. Dr. Peter Malone is a leading expert in virology, who discovered RNA transfection in 1988, and until recently was credited with the discovery of mRNA vaccine development. He has recently warned about deploying mRNA vaccines to the population at large. Concerns he voiced included the risk of ADE that was seen in the animal studies, the creation of more pathogenic variants, and he recommended they be considered only for those with the greatest risk (the elderly). For the rest of the population he recommends treatment with effective drugs, natural recovery and subsequent immunity over vaccination.

E. Molecular mimicry is defined as similar structures shared by dissimilar genes or by their protein products. Understanding this issue is critical to understanding the myriad of long-term risks. The spike protein that the COVID-19 mRNA based-gene therapy causes a vaccinated person to produce, is designed to induce an immune response, but this spike protein shares similarity to many normal human tissues. In fact, in one study where SARS-CoV-2 antibodies were screened using 55 different human tissue antigens, 28 of 55 (51%) showed reactivity. These tissues included gastrointestinal, thyroid and neurologic tissue. This implies a heightened risk of autoimmune diseases especially over time. This risk is likely greater in people with dysregulated immune systems, autoimmune diseases, or an inherent predilection for auto-immune disease

development. Due to antibodies to syncetin-1, caused by the spike protein, many have expressed concerns that this could cause an immune attack on the placenta since it contains cells called, syncytiothrophoblasts, that may be targeted with these types of antibodies.
While not yet known, there are concerns regarding this being a possible mechanism for some of the post-vaccine fetal losses seen and reported in VAERS, shown in Table 3.

F. Immune suppressive effects of COVID-19 vaccines have recently been described, which were not initially expected. Dr. Ryan Cole, CEO and Medical Director, of Cole Diagnostics, has reported on multiple COVID-19 gene-based vaccine induced pathologic changes that he has been observing. As a pathologist, with expertise in immunology and virology, his lab has screened multiple blood and tissue specimens. He has reported a post-vaccine drop in CD8 positive T-cells. This is resulting in immune suppression in some vaccinated patients. Concurrently with these immune suppressive changes, he has also noted a significant uptick in reactivation of multiple herpes family viruses such as varicella zoster virus, herpes simplex virus, Epstein Barr virus, as well as human papilloma virus in cervical specimens, and 20-fold increase pox virus-induced molluscum contagiosum. He believes these findings are due to vaccine associated weakening of the immune system. Of note, similar changes are seen in people who are actively infected with COVID-19. This is not surprising as the virus can cause a decrease in the cytotoxic (pathogen killing) potential of T-cells and NK T-cells. These changes can last for months as well. The duration of vaccine associated changes in unknown.

G. Molecular biologist, Christine Mayr, MD, PhD, researcher at Memorial Sloan Kettering Institute, has reported that mRNA may reduce tumor suppressor genes and result in an increase in cancer. This has not been reported with the COVID 19 mRNA vaccines specifically but remains a concern and a potential risk. Severe immune suppression, especially if protracted, could also contribute to cancer risk.

H. Neurodegenerative illnesses have been seen and are felt to be a long-term risk with the COVID-19 gene therapies. Dr. Luc Montagnier, virologist, researcher, and Nobel Laureate is one of several researchers that have also brought this concern to the forefront. Some sequences of the spike protein resemble that of the prion-like domains in the brain. Prion diseases are due to misfolding of proteins called prion proteins, which is a rare cause of a progressive decline in brain function. In people with prion disease, misfolded prion protein can bind to healthy prion protein, which causes the healthy protein to also fold abnormally. This disease is usually fatal. COVID-19 vaccines may induce prion-based degenerative disease, causing progressive brain deterioration. Another author concluded that mRNA-based vaccines may cause ALS, front temporal lobar degeneration, Alzheimer's disease, and other neurological degenerative diseases.

I. Dr. Byram Bridle, a viral immunologist and vaccine researcher, at University of Guelph, in Ontario, was awarded a large government grant for COVD-19 vaccine development. He recently stated that they, the vaccine designers, made a big mistake by using the spike protein as the target. He further states that the scientists did not realize at the time that the spike protein is the pathogenic portion of the virus. He also pointed out that Japanese data, looking at mRNA COVID-19 vaccine bio-distribution, after the mRNA injection yielded an unexpected surprise including the extensive uptake of the mRNA gene-based vaccine in the blood and increased concentration around the ovaries. This has heightened additional concerns regarding infertility.

J. Dr. Janci Chunn Lindsay, Ph.D., molecular biologist and toxicologist with over 30 years of scientific experience, and pre-clinical experience with vaccine induced sterility in animals, provided her testimony before the CDC. Dr. Lindsay implored the CDC to cease mass vaccination and warned them that we could leave an entire generation infertile, stating that there was credible evidence that COVID-19 vaccines could induce cross-reactivity with syncytin, and reproductive proteins in sperm, ova, and the placenta, which could impair pregnancy and the ability for some women to carry a fetus to term.

Similarly, well-respected, Pfizer scientist, Dr. Michael Yeadon, former Vice President of Pfizer and respected immunologist, has been very outspoken regarding his concerns over the COVID-19 gene-based mRNA vaccines. Among his greatest concerns was the ill-founded recommendation that pregnant women be vaccinated with the COVID-19 gene therapies, as there are no pre-clinical animal studies examining fetal risk, reproductive risk, and no long-term human data that would typically be required before any drug would be approved for use in pregnancy.

K. Thrombotic complications are well recognized with all COVID-19 and COVID-19 gene-based vaccines. We know the vaccines cause vaccinated people to express the pathogenic or disease-causing part of the virus, the spike protein. So, the vaccine can cause similar diseases to an active COVID-19 infection. The spike protein expressed in the blood vessel lining (vascular endothelium) can yield a prothrombotic state, which explains the pulmonary emboli, deep vein thromboses, strokes, and myocardial infarctions that have been reported.

L. Blood donation safety is also a significant area of concern and uncertainty. This likely will affect our blood supply. Should vaccinated people be allowed to donate blood? Transfusing an infant, young child, or a tenuous older person who may already be seriously ill with blood, containing spike proteins, may result in unintended harm.

M. All treatment considerations must weigh risk and benefit. Risks of the COVID-19 gene therapies have been difficult to know fully due to censorship, under-recognized toxicities, and under-reported side effects. The best available data we have comes from the Vaccine Adverse Event Reporting System (VAERS).

Significant morbidity and death have been seen due to the COVID-19 vaccines. These numbers continue to rise daily. You will see that the current VAERS data as of August 6, 2021 showed 571, 830 reports of vaccine injury in the US alone; see table 3. A 2009 Harvard study showed that the data reported in VAERS likely only accounts for 1% of vaccine side effects being experienced by those that have been vaccinated. So, the numbers shown likely represent a significant under-representation of vaccine associated injuries. In the current data we also see that at least 12,791 people have died related to vaccine associated injury. Again, these statistics represent the United States only. Increase numbers have also been seen in Europe and other countries. The global side effect and toxicity impact must be astounding. Moreover, you will see that at least 42,727 people experienced anaphylaxis, other severe allergic reactions, or a life-threatening event. Furthermore, at least 16,044 people have become permanently disabled. Dr. Peter McCullough recently reported that the COVID vaccine death rate is likely at least 50,000,

based on data from a whistleblower inside the Centers for Medicare and Medicaid services and two whistleblowers inside the CDC. These vaccine toxicities and the death rate are staggering and unprecedented. The cure cannot be worse than the disease. In fact, these numbers exceed all vaccine reactions and toxicities for all other vaccines combined reported in the last 20 years. Unforeseen toxicities continue to be discovered, such as the recent association of COVID-19 vaccination and myocarditis in young people after COVID-19 vaccination. Some of these cases were severe and will likely lead to life-long cardiac limitations, disability, and early death.

Table 3. VAERS. Depicted are some of the COVID-19 associated events and the numbers reported as of **8/6/2021.** The total reported events were 571,830 events as of that date.

EVENT	Deaths	Hospitalizations	Urgent Care Visits	Office Visits	Severe Allergic Reactions
NUMBER	12,791	51,242	70,666	95,887	24,305
EVENT	Anaphylaxis	Bell's Palsy	Miscarriages	Myocardial Infarction	Low Platelets
NUMBER	5,282	4,461	1.505	5,590	2,554
EVENT	Myocarditis/Pericarditis	Permanent Disability	Life Threatening	Shingles	
NUMBER	4,371	16, 044	13,140	6,784	

N. Dangers of vaccination in the setting of an ongoing pandemic are known. Dr Luc Montagnier, Nobel Prize winning virologist , and Dr. Geert Vanden Bossche, a PhD scientist and respected vaccine designer, involved in vaccine development, have warned that you should not vaccinate in the midst of a pandemic as you will generate many COVID-19 mutants. Mass vaccination results in immune escape by driving emergence of new variants that bypass vaccine immunity, which is likely the reason for the emergence of the new variants. Dr. Janci Chunn Lindsay, Ph.D., mentioned earlier, in her testimony to the CDC, has also affirmed that there was strong evidence of immune escape and that under the pandemic pressure, more lethal mutants would be likely forthcoming and that the COVID-19 vaccines could cause more deaths due to ADE and the generation of resistant variants across the population than would be seen without COVID-19 gene based vaccine intervention. That is, there is evidence that the vaccines can, and are likely, making the pandemic worse.

O. Importantly, all the current COVID-19 gene-based vaccines are experimental and as we have discussed, lack pre-clinical animal studies as well as long-term safety studies in animals and human. All available COVID-19 vaccines that are currently being used are under the experimental use authorization (EUA) permitted by the Federal Drug Administration (FDA). An EUA is a mechanism to facilitate the availability and use of medical countermeasures, including vaccines during public health emergencies. Criteria required to declare a drug or vaccine be made available under an EUA include that there are no adequate approved or available alternatives. It is clear based on the depth and breadth of the data on ivermectin and hydroxychloroquine combinations, vitamin D, and zinc, that these data were intentionally suppressed to push forward COVID-19 gene-based vaccines under the EUA. See section 1, subsection R. on alternatives for prophylaxis and treatment.

P. Contrary to current recommendations, patients do not need to be vaccinated if they have already been infected with COVID-19. Evidence of prolonged immunity after patients who were infected with a previous coronavirus, SARS, in 2003, demonstrated continued protection from re-infection and that this did provide some protection against COVID-19. There is mounting evidence that COVID-19 vaccination in someone who has already had the infection likely has no additional benefit and that these patients have a significant increased risk of vaccine related reactions or injury. Dr. Peter McCullough, internist, cardiologist, epidemiologist, and Professor of Medicine at Texas A & M College of Medicine in Dallas, who has become a leader in the medical response to the COVID-19 disaster, has asserted that COVID-19 vaccination in those previously infected with COVID-19 is unnecessary, unfounded, and unsafe. Interestingly, a George Mason law professor was granted a legal exemption from the university (COVID-19 gene-based) vaccine mandate based on a natural immunity law suit.

Q. The COVID-19 gene-based vaccine doesn't prevent transmission (or protect patients, which has been argued). The CDC has recently changed its recommendations due to an increase in infections in those vaccinated and has also warned of the likelihood of virus transmission in those who have been fully vaccinated, requesting all people vaccinated and unvaccinated continue to wear masks indoors. While mask utility is arguable, the CDC now says that even those people fully vaccinated for COVID-19 are at risk of acquiring the delta variant of COVID-19 and spreading the virus. They concluded the delta variant is highly contagious, likely to be more severe, and that breakthrough infections may be as transmissible as those that are unvaccinated.

R. Alternative therapies exist and must be considered in the prophylaxis and the treatment of COVID-19 infections. The suppression of data and vilification of providers employing these treatments for at risk or sick patients is highly unusual.

There are effective, safe, inexpensive preventive options and treatments for COVID–19. Interestingly, early on in the pandemic several doctors noted that the incidence of COVID-19 was decreased in countries with high malaria rates and had minimal to no deaths. Chloroquine is used heavily in these regions. This led to interest and exploration of chloroquine and hydroxychloroquine to treat COVID-19. Hydroxychloroquine alone or in combination continues to be a source of study and controversy. The Lancet reported a negative hydroxychloroquine study that was widely used to malign this treatment and any using it. Subsequently, it was discovered that the Lancet study was completely fabricated and later retracted, but much damage had already been done by the negative press reports. The best studies with hydroxychloroquine are typically combined with zinc with or/without azithromycin. Hydroxychloroquine is currently one of the treatments recommended by Dr McCullough and others, published in The American Journal of Medicine for early management of those with a COVID-19 infection.

Additionally, there are multiple compelling studies and meta-analyses (groups of trials) showing a significant benefit with ivermectin, an FDA approved anti-parasitic drug, being used to treat and prevent COVID-19. The real-time meta-analysis, on https://ivmmeta.com/ shows a statistically significant improvement in mortality, hospitalizations, recovery, and viral clearance

in those who were treated with ivermectin. Significant benefits were seen with ivermectin for both prophylaxis and treatment. Early intervention with ivermectin resulted in much better outcomes than later institution of the therapy. The authors point out that all practical, effective, and safe means should be used to prevent or treat COVID-19 and that those denying the efficacy of treatments share responsibility for COVID-19 becoming endemic and for the increased mortality, morbidity, and collateral damage

Additional supplements including vitamin D, vitamin C, zinc, n-acetyl cysteine, and quercetin have all been found to be potentially beneficial in the treatment, lessening the severity, or prevention of COVID-19.

In a retrospective study by Dr Raharusun, he found that the mortality of patients with a normal Vitamin D level markedly reduced at 4%. Please see Figure. 1. Note the significant drop in mortality based on Vitamin D levels alone. A standard recommendation should include zinc and vitamin D supplementation for all people, especially in winter months to help prevent COVID-19 and to lessen risk or development of severe disease.

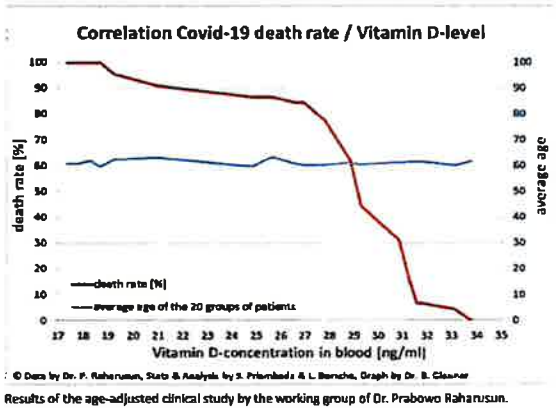


Figure 1. This graph demonstrates the COVID-19 death rate drops dramatically in patients with a normal Vitamin D level.

Everything in medicine must be weighed. Risk of any treatment must be beneficial to the person receiving it and that perceived benefit must exceed the toxicity of the treatment.

S. If COVID 19 gene therapies are safe, why are the pharmaceutical companies indemnified? Furthermore, why are vaccine mandates permissible around the country and not required at the White House, the FDA, the CDC, the World Health Organization, Pfizer, Moderna, or Johnson and Johnson?

T. Alternatives to COVID-19 gene-based vaccination exist, as I have briefly touched upon, and should be discussed with all patients when obtaining informed consent regarding the vaccines. In my experience, this is not happening due to the suppression of data; negative media manipulation, and absence of critical thinking by many providers. Many providers are not questioning the science or looking at the data, they are busy, and are trusting Dr. Fauci and the

CDC. Unfortunately, many of these people and their organizations are swayed by their funding resources. So, critical examination of the science is required in order to follow the science.

U. Open borders with thousands of infected illegal immigrants entering the US, poses a much greater risk of COVID-19 dissemination than whether your nurse has had the COVID-19 gene-based vaccine.

2.Those refusing the current COVID-19 gene-based vaccines under employer mandates are justified in doing so.

A. Based on the science, the low mortality risk to most of the population, the long-term risks for all patients who have received these gene based COVID-19 vaccines, this must be voluntary and requires informed consent, and a weighing of the risks and benefits.

B. Mandated uniform deployment of the COVID-19 gene-based therapies are a clear violation of the Nuremberg Code and Geneva Convention code of conduct for ethical experimentation in humans.

C. Caution is required. In response to the recent mandate for vaccination of the military service personnel, Commander J.H. Furman of the US NAVY warns that the results could conceivably be catastrophic. "The forced vaccination of all military personnel with the present COVID-19 vaccines may compromise U.S. national security due to the unknown extent of serious vaccine complications," writes Furman. "Further study is needed before committing the Total Force to one irreversible experimental group. Initial reports leave more concern for the COVID-19 vaccinations than the virus itself for the (at present) exceptionally healthy military population."

This is a very valid concern given this young, healthy population, who are mission critical. Moreover, I think frontline workers such as paramedics, firemen, police officers, physicians, nurses and other hospital personnel should have this issue approached with the same caution. This has the potential to significantly cripple the capability of our nation to be able to protect citizens as well as to care for them in the event the pandemic worsens. Medical providers can do little to nothing to help other sick patients if they too become casualties themselves, suffering from COVID resistant variants and/or antibody dependent enhancement.

3. The issues and extent of the COVID fraud is vast and concerns regarding the depth and breadth continue to be defined. Censorship of news continues to be a challenge and disinformation is prolific.

A. One such issue is the PCR test for COVID which is being used inappropriately and is flawed. There is currently no gold standard test for COVID-19 since the virus has never been properly purified or visualized. Reliable analytical data is critical for the correct determination of the real presence or absence of COVID-19 infection. The genetic sequences used in PCR to detect suspected SARS-CoV-2 to diagnosis cases of illness and death attributed to the infection are present in many sequences of the human genome and multiple other viruses. Dr. Stephen Bustin, a leading expert in PCR, says that under certain conditions anyone can test positive. The arbitrary increased number of cycles to amplify DNA yielded in a significant number of false positive which in same cases where as high as 90%. Additionally, the current COVID-19

(SARS-CoV-2) testing cannot distinguish between Influenza infection or COVID-19. This is likely why the Influenza incidence and mortality dropped significantly in 2020, as many of those cases were being attributed to COVID-19. This is now acknowledged by the FDA. The FDA is revoking the authorization of at least one of their PCR based COVID-19 tests due to concerns about accuracy, despite this test being used in millions of people in the US. However, this test continues to be used until December of 2021. Lastly, the frequent testing of asymptomatic patients is unscientific, useless, and a waste of money.

B. The mortality statistics used initially were greatly over-inflated. If anyone died (even from a gunshot wound) and tested positive (despite the flawed PCR methodology) that death was counted as a COVID-19 death.

C. Masks do not work. Initially, Dr Fauci recommended against masks because of the science. Then he recanted and recommended one, then subsequently two masks because of the science. The science demonstrates that the mask pore size in all masks is greater than the 0.12-micron (range 0.06-0.14 microns) size of the COVID-19 virus. This includes the N95 masks which have a pore size of 0.3 microns. This alone does not consider some of the other dynamics. However, even in the best scenario the N-95 mask would only filter and/or trap up to 95% of particles. This assumes the virus itself is always attached to something else such as water droplets or aerosols. There is literature to show masks may have a detrimental effect on mask wearers. Among these are an increase in skin infections, bacterial pneumonia, suppression of the immune system, dental caries and a new research has shown that cloth mask may increase viral transmission because they cause further aerosolization of the drops (making them smaller) which may result in increased viral infectivity. Furthermore, mask wearing for prolonged periods can increase CO2 retention and hypoxia (lowering of oxygen). In fact, the N-95 masks may lower oxygen by 20% which is significant.

D. There has been suppression and unprecedented restrictions of the clinical, off-label, use of FDA approved medicines such as hydroxychloroquine and/or ivermectin, which physicians have done for years in the care of their patients. This is an acceptable practice. However, once the pandemic began, doctors were suddenly prohibited from using hydroxychloroquine based on previously known data of efficacy. In fact, some physicians, including Dr Simone Gold, a lawyer and emergency room physician, were fired for prescribing hydroxychloroquine to a sick patient, suffering from COVID-19. Dr. Gold subsequently went on to establish the American Frontline Doctors, an advocacy group, still using hydroxychloroquine and ivermectin combinations to this day with good success.

E. An emergency use authorization was only possible if no effective therapy was available, so clinical data on the use, safety and effectiveness of hydroxychloroquine and ivermectin were suppressed. Factually inaccurate information flourished in the media.

F. Dr. Anthony Fauci, Director of the National Institute of Allergy and Infectious Diseases (NIAID), has recently been linked to funding illegal, gain of function, coronavirus research with tax-payer funding through the lab in Wuhan, China.

However, I would like to reference the meticulous tome of work by Dr David Martin, PhD. Dr. David Martin founded M·CAM ® in 1998 and has served as its CEO and Chairman since

that time. M·CAM ® has been an international intangible asset underwriter and analyst firm, spanning work in innovation finance, trade, and intangible asset finance. He has published a compendium, cataloguing the fraud committed by Dr Anthony Fauci, other scientists, and other government agencies. This has shown foreign aid to the Wuhan Institute of Virology in China, which Dr. Fauci and the NIAID granted tax-payer funding for gain of function research. As outlined by Dr Martin, in the document he methodically compiled, titled, "The Fauci/COVID-19 Dossier- This document is prepared for humanity" has been monitoring possible violations of the 1925 Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or other Gases, and of Bacteriological Methods of Warfare (the Geneva Protocol) 1972 Convention on the Prohibition of the Development, Production, and Stockpiling of Bacteriological and Toxin Weapons and Their Destruction (the BTWC). In their 2003-2004 Global Technology Assessment: Vector Weaponization M·CAM highlighted China's growing involvement in Polymerase Chain Reaction (PCR) technology with respect to joining the world stage in chimeric construction of viral vectors. Since that time, on a weekly basis, we have monitored the development of research and commercial efforts in this field, including, but not limited to, the research synergies forming between the United States Centers for Disease Control and Prevention (CDC), the National Institutes for Allergies and Infectious Diseases (NIAID), the University of North Carolina at Chapel Hill (UNC), Harvard University, Emory University, Vanderbilt University, Tsinghua University, University of Pennsylvania, many other research institutions, and their commercial affiliations.

Dr. Martin points out on page on 2 the Covid-19 Dossier, *that "on April 19, 2002 – the Spring before the first SARS outbreak in Asia – Christopher M. Curtis, Boyd Yount, and Ralph Baric filed an application for U.S. Patent 7,279,372 for a method of producing recombinant coronavirus. In the first public record of the claims, they sought to patent a means of producing, "an infectious, replication defective, coronavirus." This work was supported by the NIH grant referenced above and GM63228. In short, the U.S. Department of Health and Human Services was involved in the funding of amplifying the infectious nature of coronavirus between 1999 and 2002 before SARS was ever detected in humans. Furthermore, he goes to say in the COVID-19 Dossier, pages 5-6, "In their majority opinion in 2013, the U.S. Supreme Court made it abundantly clear that the Court had "long held" that nature was not patentable. Merely isolating DNA does not constitute patentable subject matter. In their patent, the CDC made false and misleading claims to the United States Patent & Trademark Office by stating that, "A newly isolated human coronavirus has been identified as the causative agent of SARS, and is termed SARS-CoV."4 No "causal" data was provided for this statement. When they filed their patent application on April 25, 2003 their first claim (and the only one that survived to ultimate issuance over the objection of the patent examiner in 2006 and 2007) was the genome for SARS CoV. While this patent is clearly illegal under 35 U.S.C. §101, not only did the CDC insist on its granting over non-final and final rejections, but they also continued to pay maintenance fees on the patent after the 2013 Supreme Court decision confirmed that it was illegal. In addition, the CDC patented the detection of SARS CoV using a number of methods including reverse transcription polymerase chain reaction (RT-PCR). With this patent, they precluded anyone outside of their licensed or conspiring interest from legally engaging in independent verification of their claim that they had isolated a virus, that it was a causative agent for SARS, or that any therapy could be effective against the reported pathogen. It is important to note that the CDC's*

patent applications were also rejected in non-final and final rejections for ineligibility under 35 U.S.C. § 102 for being publicly disclosed prior to their own filing. In the first non-final rejection, the USPTO stated that the CDC's genome was published in four Genbank accession entries on April 14, 18, and 21, 2003 with identity ranging from 96.8% to 99.9% identical sequences.5 Dr. Fauci knew, and failed to disclose evidence that the CDC patent was illegal, based on work he had funded in the years leading up to the SARS outbreak. After seeking an illegal patent, petitioning to override the decision of an examiner to reject it, and ultimately prevailing with the patent's grant, the CDC lied to the public by stating they were controlling the patent so that it would be "publicly available".6 Tragically, this public statement is falsified by the simple fact that their own publication in Genbank had, in fact, made it public domain and thereby unpatentable. This fact, confirmed by patent examiners, was overridden by CDC in a paid solicitation to override the law. While not covered under 35 U.S.C. §101, Dr. Fauci's abuse of the patent law is detailed below. Of note, however, is his willful and deceptive use of the term "vaccine" in patents and public pronouncements to pervert the meaning of the term for the manipulation of the public. In the 1905 Jacobson v. Mass case, the court was clear that a PUBLIC BENEFIT was required for a vaccine to be mandated. Neither Pfizer nor Moderna have proved a disruption of transmission. In Jacobson v. Massachusetts, 197 U.S. 11 (1905), the court held that the context for their opinion rested on the following principle: "This court has more than once recognized it as a fundamental principle that 'persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state..." The Moderna and Pfizer "alleged vaccine" trials have explicitly acknowledged that their gene therapy technology has no impact on viral infection or transmission whatsoever and merely conveys to the recipient the capacity to produce an S1 spike protein endogenously by the introduction of a synthetic mRNA sequence. Therefore, the basis for the Massachusetts statute and the Supreme Court's determination is moot in this case. Further, the USPTO, in its REJECTION of Anthony Fauci's HIV vaccine made the following statement supporting their rejection of his bogus "invention."

Dr. Martin goes on to say on page 7-11, "By no later than April 11, 2005, Dr. Anthony Fauci was publicly acknowledging the association of SARS with bioterror potential. Leveraging the fear of the anthrax bioterrorism of 2001, he publicly celebrated the economic boon that domestic terror had directed towards his budget. He specifically stated that NIAID was actively funding research on a "SARS Chip" DNA microarray to rapidly detect SARS (something that was not made available during the current "pandemic") and two candidate vaccines focused on the SARS CoV spike protein.7 Led by three Chinese researchers under his employment – Zhi-yong Yang, Wing-pui Kong, and Yue Huang – Fauci had at least one DNA vaccine in animal trials by 2004.8 This team, part of the Vaccine Research Center at NIAID, was primarily focused on HIV vaccine development but was tasked to identify SARS vaccine candidates as well. Working in collaboration with Sanofi, Scripps Institute, Harvard, MIT and NIH, Dr. Fauci's decision to unilaterally promote vaccines as a primary intervention for several designated "infectious diseases" precluded proven therapies from being applied to the sick and dying.9 The CDC and NIAID led by Anthony Fauci entered into trade among States (including, but not limited to working with EcoHealth Alliance Inc.) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences) through the 2014 et seq National Institutes of Health Grant R01AI110964 to exploit their patent rights. This research was known to involve

surface proteins in coronavirus that had the capacity to directly infect human respiratory systems. In flagrant violation of the NIH moratorium on gain of function research, NIAID and Ralph Baric persisted in working with chimeric coronavirus components specifically to amplify the pathogenicity of the biologic material. By October 2013, the Wuhan Institute of Virology 1 coronavirus S1 spike protein was described in NIAID's funded work in China. This work involved NIAID, USAID, and Peter Daszak, the head of EcoHealth Alliance. This work, funded under R01AI079231, was pivotal in isolating and manipulating viral fragments selected from sites across China which contained high risk for severe human response.10 By March 2015, both the virulence of the S1 spike protein and the ACE II receptor was known to present a considerable risk to human health. NIAID, EcoHealth Alliance and numerous researchers lamented the fact that the public was not sufficiently concerned about coronavirus to adequately fund their desired research.11 Dr. Peter Daszak of EcoHealth Alliance offered the following assessment: "Daszak reiterated that, until an infectious disease crisis is very real, present, and at an emergency threshold, it is often largely ignored. To sustain the funding base beyond the crisis, he said, we need to increase public understanding of the need for MCMs such as a pan-influenza or pan-coronavirus vaccine. A key driver is the media, and the economics follow the hype. We need to use that hype to our advantage to get to the real issues. Investors will respond if they see profit at the end of process, Daszak stated." Economics will follow the hype. The CDC and NIAID entered into trade among States (including, but not limited to working with University of North Carolina, Chapel Hill) and with foreign nations (specifically, the Wuhan Institute of Virology and the Chinese Academy of Sciences represented by Zheng-Li Shi) through U19AI109761 (Ralph S. Baric), U19AI107810 (Ralph S. Baric), and National Natural Science Foundation of China Award 81290341 (Zheng-Li Shi) et al. 2015-2016. These projects took place during a time when the work being performed was prohibited by the United States National Institutes of Health. The public was clearly advised of the dangers being presented by NIAID-funded research by 2015 and 2016 when the Wuhan Institute of Virology material was being manipulated at UNC in Ralph Baric's lab. "The only impact of this work is the creation, in a lab, of a new, non-natural risk," agrees Richard Ebright, a molecular biologist and biodefence expert at Rutgers University in Piscataway, New Jersey. Both Ebright and Wain-Hobson are long-standing critics of gain-of-function research. In their paper, the study authors also concede that funders may think twice about allowing such experiments in the future. "Scientific review panels may deem similar studies building chimeric viruses based on circulating strains too risky to pursue," they write, adding that discussion is needed as to "whether these types of chimeric virus studies warrant further investigation versus the inherent risks involved". But Baric and others say the research did have benefits. The study findings "move this virus from a candidate emerging pathogen to a clear and present danger", says Peter Daszak, who co-authored the 2013 paper. Daszak is president of the EcoHealth Alliance, an international network of scientists, headquartered in New York City, that samples viruses from animals and people in emerging-diseases hotspots across the globe. Studies testing hybrid viruses in human cell culture and animal models are limited in what they can say about the threat posed by a wild virus, Daszak agrees. But he argues that they can help indicate which pathogens should be prioritized for further research attention." Knowing that the U.S. Department of Health and Human Services (through CDC, NIH, NIAID, and their funded laboratories and commercial partners) had patents on each proposed element of medical counter measures and their funding, Dr. Fauci, Dr. Gao (China CDC), and Dr. Elias (Bill and Melinda Gates Foundation) conspired to

commit acts of terror on the global population – including the citizens of the United States – when, in September 2019, they published the following mandate: "Countries, donors and multilateral institutions must be prepared for the worst. A rapidly spreading pandemic due to a lethal respiratory pathogen (whether naturally emergent or accidentally or deliberately released) poses additional preparedness requirements. Donors and multilateral institutions must ensure adequate investment in developing innovative vaccines and therapeutics, surge manufacturing capacity, broad-spectrum antivirals and appropriate nonpharmaceutical interventions. All countries must develop a system for immediately sharing genome sequences of any new pathogen for public health purposes along with the means to share limited medical countermeasures across countries. Progress indicator(s) by September 2020 • Donors and countries commit and identify timelines for: financing and development of a universal influenza vaccine, broad spectrum antivirals, and targeted therapeutics. WHO and its Member States develop options for standard procedures and timelines for sharing of sequence data, specimens, and medical countermeasures for pathogens other than influenza. • Donors, countries and multilateral institutions develop a multi-year plan and approach for strengthening R&D research capacity, in advance of and during an epidemic. • WHO, the United Nations Children's Fund, the International Federation of Red Cross and Red Crescent Societies, academic and other partners identify strategies for increasing capacity and integration of social science approaches and researchers across the entire preparedness/response continuum." As if to confirm the utility of the September 2019 demand for "financing and development of" vaccine and the fortuitous SARS CoV-2 alleged outbreak in December of 2019, Dr. Fauci began gloating that his fortunes for additional funding were likely changing for the better. In a February 2020 interview in STAT, he was quoted as follows: ""The emergence of the new virus is going to change that figure, likely considerably, Fauci said. "I don't know how much it's going to be. But I think it's going to generate more sustained interest in coronaviruses because it's very clear that coronaviruses can do really interesting things." section 802 of the USA PATRIOT Act (Pub. L. No. 107-52) expanded the definition of terrorism to cover "domestic," as opposed to international, terrorism. A person engages in domestic terrorism if they do an act "dangerous to human life" that is a violation of the criminal laws of a state or the United States, if the act appears to be intended to: (i) intimidate or coerce a civilian population; (ii) influence the policy of a government by intimidation or coercion; Dr. Anthony Fauci has intimidated and coerced a civilian population and sought to influence the policy of a government by intimidation and coercion. With no corroboration, Dr. Anthony Fauci promoted16 Professor Neil Ferguson's computer simulation derived claims that, "The world is facing the most serious public health crisis in generations. Here we provide concrete estimates of the scale of the threat countries now face. "We use the latest estimates of severity to show that policy strategies which aim to mitigate the epidemic might halve deaths and reduce peak healthcare demand by two-thirds, but that this will not be enough to prevent health systems being overwhelmed. More intensive, and socially disruptive interventions will therefore be required to suppress transmission to low levels. It is likely such measures – most notably, large scale social distancing – will need to be in place for many months, perhaps until a vaccine becomes available." Reporting to the President that as many as 2.2 million deaths may result from a pathogen that had not yet been isolated and could not be measured with any accuracy, Dr. Fauci intimidated and coerced the population and the government into reckless, untested, and harmful acts creating irreparable harm to lives and livelihoods.18 Neither the Imperial College nor the "independent" Institute for Health Metrics

and Evaluation (principally funded by the Bill and Melinda Gates Foundation)19 had any evidence of success in estimating previous burdens from coronavirus but, without consultation or peer-review, Dr. Fauci adopted their terrifying estimates as the basis for interventions that are explicitly against medical advice.

- *The imposition of social distancing was based on computer simulation and environmental models with NO disease transmission evidence whatsoever.*

- *The imposition of face mask wearing was directly against controlled clinical trial evidence and against the written policy in the Journal of the American Medical Association. "Face masks should not be worn by healthy individuals to protect themselves from acquiring respiratory infection because there is no evidence to suggest that face masks worn by healthy individuals are effective in preventing people from becoming ill."*

- *In both the Imperial College and the IHME simulations, quarantines were modeled for the sick, not the healthy.*

Insisting on vaccines while blockading the emergency use of proven pharmaceutical interventions may have contributed to the death of many patients and otherwise healthy individuals. Using the power of NIAID during the alleged pandemic, Dr. Anthony Fauci actively suppressed proven medical countermeasures used by, and validated in scientific proceedings, that offered alternatives to the products funded by his conspiring entities for which he had provided direct funding and for whom he would receive tangible and intangible benefit."

G. Dr. Reiner Fuellmich, an international attorney in Europe, with a team of over 1,000 lawyers and over 10,000 medical experts, has begun legal proceedings, called the New Nuremberg Trials of 2021, against the CDC, WHO, and the Davos Group for crimes again humanity. Mr. Fuellmich and his group have brought up similar issues to include the faulty PCR testing, the mislabeling and attribution of any death with a positive PCR test as COVID related, resulting in fraudulent death certificates, as well as COVID-19 gene based vaccines concerns. They also claim that the COVID-19 gene based experimental vaccine is a violation of all 10 of the Nuremberg Codes.

H. A group of 57 leading scientists, doctors, and policy experts, including Dr. Peter McCullough, are calling into question the safety and efficacy of the current COVID-19 vaccines and are calling for an immediate end to all COVID-19 vaccine programs. I concur completely. We have alternatives with a safer track record that will not yield resistant COVID variants.

I. Conflicts of interest need to be delineated. Dr. Fauci, NIAID, CDC, WHO all receive private funding, including funding from the pharmaceutical industry. Doctors, churches, employers and community organizations are compromised. Some are offering bonuses and incentives and others are receiving bonuses based on their vaccination rates. The public is unaware of most of this.

J. The sum and substance of my key points are as follows:

- There is a great deal of concern regarding long-term safety with this new methodology and caution should be exercised.
- Many people are being coerced into receiving an experimental gene therapy never before used in humans. This is a clear violation of the Nuremberg code.
- Many patients do not recognize that this gene vaccine is an experiment and they are not receiving appropriate informed consent including the discussion regarding no treatment or alternative treatments.
- Most patients do not need and will not benefit from the COVID-19 gene base therapies but will still incur long-term risk.
- All people have a right to decide for themselves whether they want to receive this experimental gene-based vaccine or not after appropriate inform consent.
- Mandating this experimental therapy in any child or person is wrong. Mandating the COVID-19 gene-based vaccine in frontline workers and our military is short sighted and potentially compromises our nation and our communities. These are mission critical personnel and the risking of their health in this setting is senseless and could lead to more deaths (from patients who cannot be care for) or national security issues.
- These gene-based vaccines do not protect them from getting the COVID-19 infection, transmitting the infection, or the development of resistant variants, and may put them at risk of antibody dependent enhancement or another serious vaccine associated injury.
- To mandate that children receive this experimental gene therapy is highly inappropriate, based on their negligible mortality with the coronavirus infection, low transmissibility which has been documented in children, and their long life expectancy in which they will be at high risk of future toxicity, potential infertility, and the potential risk of perpetual antibody dependent enhancement with coronavirus, influenza, or other respiratory viruses. It is my opinion that mandating that children, adolescents, or young adults receive this gene base therapy is criminal.
- Dr. Fauci, the NIAID, and others are complicit in fraud as categorically outlined by Dr. Martin

Under penalty of perjury, I hereby declare and affirm that the above stated facts, to the best of my knowledge, are true and correct, and I reserve the right to supplement my opinion. I present my opinions based on a reasonable degree of medical certainty. I give these opinions based on my attached curriculum vitae, my education, my work history, my experience and a review of all the scientific data.

DATED this 20th day of August, 2021

Signature

JAMIE K. WASELENKO

Printed Name

NOTARY ACKNOWLEDGMENT

State of KY)

) **(Seal)**

County of Boyd)

The foregoing instrument was acknowledged before me this 20 day of August, 2021, by the undersigned, Jamie Waselenko, who is personally known to me or satisfactorily proven to me to be the person whose name is subscribed to the within instrument.

Signature

Lauren N. Keith

Notary Public

My Commission Expires: 3-12-25

OFFICIAL SEAL
LAUREN N. KEITH
NOTARY PUBLIC - KENTUCKY
STATE-AT-LARGE
My Comm. Expires March 12, 2025
ID # KYNP25486

Curriculum Vitae

Jamie Kendrick Waselenko, MD, FACP

Career Focus: To use my 26 years of medical expertise to ensure that patients experiencing complex hematology and oncology illnesses receive the highest standard of care with compassion, professionalism and clinical excellence.

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Education

Bachelor of Arts, Major in Biology — June 1988
Wayne State University
Detroit, MI

Medical Degree — May 1992
Uniformed Services University
Bethesda, MD

Honors

Phi Beta Kappa National Honor Society	1988
Distinguished Military Graduate	1991
Alpha Omega Alpha Medical Honor Society	1991
Resident Research Award	1995
Top Oncologists in America	2012

Graduate Medical Education

Internal Medicine Internship — July 1992-June 1993
Walter Reed Army Medical Center
Washington, D.C.

Internal Medicine Residency — July 1993- June 1995
Madigan Army Medical Center
Tacoma, Washington

Hematology/Oncology Fellowship — July 1995-June 1998
Walter Reed Army Medical Center
Washington, D.C.

Translational Research — April 1997- June 1998
Johns Hopkins Oncology
Baltimore, MD

Bone Marrow Transplantation — January1998- February 1998
Johns Hopkins Oncology
Baltimore, MD

Military Training

Reserve Officer Training Corps (ROTC)	1986-1988
Officer Basic Course	1992
Operation Bushmaster (Equivalent to Combat Casualty Course)	1992
Officer Advance Course	2001

Military Service

Active duty, US Army	1988- June 2005
Honorable discharge	
Final grade: Lt. Colonel, Medical Corps	

Credentials

Certifications-

Diplomate, National Board of Medical Examiners	1993
Diplomate, American Board of Internal Medicine	Expires 2027
Diplomate, American Board of Internal Medicine *Medical Oncology*	Expires 2028
Diplomate, American Board of Internal Medicine, *Hematology*	Expires 2029
Basic Cardiac Life Support (BCLS)	(See ACLS)
Advanced Cardiac Life Support (ACLS)	(Expires March 2022)
Advanced Trauma Life Support (ATLS)	1991

Medical Licensure-

Ohio	Active
Kentucky	Active
Texas	Active
Tennessee	Pending reactivation
Virginia	Pending reactivation
Maryland	Inactive
Michigan	Pending reactivation

Civilian Practice History

Sarah Cannon Research Institute — July 2005-June 2007
250 25th Ave. N., Suite 110
Nashville, TN 37203
Phone (615) 329-7274
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Cincinnati Hematology Oncology, Inc. — Aug. 2007- Feb. 2012
2727 Madison Rd., Suite 400
Cincinnati, OH 45209
August 2007-January 2012

The Christ Hospital Medical Specialists II, LLC — Feb. 2012-June 2021
4460 Red Bank Expressway, Ste 200
Cincinnati, OH 45227
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Jamie K. Waselenko, MD, LLC Health care consulting 1773 Clough Pike, Bldg A. Batavia, OH 45103 513-519-7149	July 2021-present

Academic and Professional Appointments

Instructor, Department of Medicine Uniformed Services University of the Health Sciences, Bethesda, MD	1996-1998
Assistant Professor, Department of Medicine Uniformed Services University of the Health Sciences Bethesda, MD	1998-October 2004
Assistant Professor, Department of Medicine University of Texas Health Science Center At San Antonio San Antonio, TX	July 1999-May 2001
Clinical Assistant Professor Department of Medicine University of Maryland Greenebaum Cancer Center Staff, Stem Cell Transplant Service Baltimore, MD	Sept. 2002-May 2004
Associate Professor, Department of Medicine Uniformed Services University of the Health Sciences Bethesda, MD	Nov. 2004-June 2005
Hematopoietic Stem Cell Transplantation Service, Assistant Director Brooke Army Medical Center San Antonio, TX	July 1998-Feb.2000
Hematopoietic Stem Cell Transplantation Service, Director Brooke Army Medical Center San Antonio, TX	Feb. 2000-March 2001
Texas Transplant Institute Staff, Stem Cell Transplant Service (Weekend Coverage) Southwest Methodist Hospital San Antonio, TX	Aug. 1999-May 2001
Hematopoietic Stem Cell Transplantation Service Assistant Director Walter Reed Army Medical Center	June 2001-Feb. 2004

Washington D.C. Hematopoietic Stem Cell Transplantation Service Co-Director Walter Reed Army Medical Center Washington D.C.	Feb. 2004-June 2004
Center for the Development of Cancer Drugs and Therapeutics, Director Walter Reed Army Medical Center Washington, D.C.	June 2001-June 2004
Hematology/Oncology Department Assistant Chief Walter Reed Army Medical Center Washington D.C.	May 2002-June 2004
Armed Forces Radiobiology Research Institute Head, Military Medicine Department Bethesda, MD	July 2004-June 2005
National Naval Medical Center Clinical Staff, Hematology/Oncology Bethesda, MD	July 2004-June 2005
Sarah Cannon Blood and Marrow Transplant Program Clinical Director Nashville, TN	July 2005- July 2007
Sarah Cannon Blood and Marrow Transplant Program Collection's Facility Medical Director Nashville, TN	July 2006- July 2007
Sarah Cannon Research Institute Director, Hematologic Malignancy Research Nashville, TN	July 2005- August 2006
Sarah Cannon Research Institute Director, Leukemia Research Nashville, TN	August 2006-July 2007
Cincinnati Hematology-Oncology, Inc Vice President and Staff, Hematologist Oncólogist Cincinnati, OH	August 2007-Jan 2011
The Christ Hospital Hematology oncology attending	July 2007-present
Jamie L. Waselenko, MD, LLC Hematology oncology consultant	July 2021- present

Peer Review Positions

Institutional Co-Principal Investigator PET, CALGB Walter Reed Army Medical Center Washington, DC	May 1997-June 1998
Transfusion Practices Committee, Member Brooke Army Medical Center, San Antonio, TX	July 1998-March 2001
Quality Assurance Department Representative Brooke Army Medical Center San Antonio, TX	June 1999-March 2001
Genitourinary Tumor Board, Member Brooke Army Medical Center San Antonio, TX	July 1998-June 2000
Clinical Breast Cancer Project, Steering Committee, Member Walter Reed Army Medical Center	June 2001-June 2004
Clinical Investigation Committee Department Representative Walter Reed Army Medical Center Washington, D.C.	June 2001-June 2004
Human Use Committee Department Representative Walter Reed Army Medical Center Washington, D.C.	January 2002-June 2004
Genitourinary Tumor Board, Rotating Department Representative Walter Reed Army Medical Center Washington, D.C.	July 2001-June 2004
General Surgery Tumor Board, Rotating Department Representative Walter Reed Army Medical Center Washington, D.C.	July 2001-June 2004
Breast Cancer Tumor Board, Rotating Department Representative Walter Reed Army Medical Center Washington, D.C.	July 2001-June 2004
Strategic National Stockpile Working Group for Acute Radiation Syndrome, Panel Member	August 2002-July 2007
Weekly Tumor Board The Christ Hospital Cincinnati, OH	July 2007- Present

Blood Transfusion Committee, Member The Christ Hospital, Cincinnati, OH	November 2007-Present
Breast Tumor Board, Rotating Member St. Elizabeth South Edgewood, Ky	July 2007- August 2010
Continuing Medical Education Committee, Member The Christ Hospital Cincinnati, OH	Sept 2011-Jan. 2019
Utilization Review Committee, Member The Christ Hospital Cincinnati, OH	Sept. 2014-Nov. 2014
Breast Tumor Board, Rotating Member The Christ Hospital Cincinnati, OH	Sept. 2011- Present

Professional Memberships/Affiliations
American College of Physicians, Fellow
American Society of Clinical Oncology, Member
American Society of Hematology, Member
American Society for Bone Marrow Transplantation, Member
Alpha Omega Alpha Medical Honor Society, Member
American Association of Blood Banks (AABB), Member
Ohio State Medical Association, Member

Patents and Technology Licenses:
Combination therapy for lymphoproliferative diseases. Byrd JC, Grever ME, Flinn IW, Waselenko JK. Patent no. 6,316,435

Publications
A. Abstracts:
Medical Treatment for Radiation Casualties. Goans RE, Waselenko JK. NCRP Meeting 14 April, 2004, Crystal City, VA

Morgan TM, Waselenko JK, Buda-Okreglak E, McGettigan C , Myhand. Relapse of Acute Eosinophilic Leukemia(AEL) in a Female Patient with t(5;12)(q31;p13) and Negative TEL-PDGF Receptor Beta during G-CSF Mobilization. Blood 102: 241b (Abstract 4686)

McGettigan C, Morgan T, Myhand R, Dutcher B, Waselenko J, Buda-Okreglak E. Rasburicase Causing Rapid Decline of Uric Acid (UA) And Resolution of Acute Renal Failure (ARF) in a Patient with Refractory Burkitt's Leukemia (BL) and Severe Tumor Lysis Syndrome (TLS). Blood 102: 261b (Abstract 4770)

Belford AM, Myles O, Myhand RC, Wang J, Magill A, Waselenko JK. Thrombotic microangiopathy (TMA), encephalitis, and seizures due to human herpes virus-6 (HHV-6) reactivation in an adult receiving high-dose melphalan with autologous peripheral stem cell transplantation (ASCT). Biol Blood Marrow Transplant 9:112, 2003,(Abstract 157)**(Presented as a poster at the 2003IBMTR/ABMTR)**

The effect of glutamine on disease progression in multiple myeloma (MM) patients receiving high-dose melphalan. Crook J, Waselenko JK, Myhand RC. Biol Blood Marrow Transplant 9: 113, 2003, (Abstract 161)

Gorak E, Waselenko JK, Myhand RC. Frequent hepatic toxicity in breast cancer patients receiving infusional paclitaxel, cisplatin and cyclophosphamide (PCC) and autologous stem cell transplant (SCT). Blood 100: 433b, 2002, (Abstract 5304)

Myhand R, Gorak E, Mitchell L, Jamison PB, and Waselenko JK. Increased incidence of symptomatic catheter related pulmonary emboli (PE) related to change in catheter brand in patients receiving high dose chemotherapy with stem cell support (HDCT). Blood 100: 435b, 2002, (Abstract 5312)

Waselenko JK, Crook J, Murphy T, and Myhand R. Long-term survival in a patient with refractory primary mediastinal non-seminomatous germ cell tumor (MGCT) who failed tandem transplant and was subsequently salvaged with surgery, a third course of high-dose chemotherapy, and mediastinal irradiation. Blood 100: 480b, 2002, (Abstract 5504)

Waselenko JK, Burrows A, Lucas M, Ekstrand JR, Myhand RC, Edenfield WJ, Byrd JC. Low dose recombinant IL-2 following high-dose chemotherapy (HDC) and autologous peripheral blood stem cell transplantation (PBSCT) in patients with chronic lymphocytic leukemia (CLL), mantle cell lymphoma (MCL), and follicular lymphoma (FL). Blood 96: 350b, 2000, (Abstract 5268)

Byrd JC, Murphy T, Lucas MS, Howard RS, Goodrich A, Park K, Pearson M, Buj V, Grever MR, Waselenko JK, Flinn IW. Thrice weekly rituximab demonstrates significant activity in chronic lymphocytic leukemia. Blood 96: 837a, 2000 (Abstract 3615)

Byrd J.C., Waselenko J.K., Shinn C.A., Willis C.R., Park K, Goodrich A., Lucas M.S., Grever M.R., Flinn I.W. Biologic study of theophylline followed by pentostatin and chlorambucil: Favorable activity concurrent with in vivo down-modulation of bcl-2 in chronic lymphocytic leukemia cells. Blood 96: 755a, 2000 (Abstract 3266)
(Presented as a poster at the 2000 American Society of Hematology meeting)

Waselenko JK, Caton J, Atkins MY, Vukelja S, Coleman TA, Myhand R. Salvage chemotherapy significantly prolongs survival in patients with breast cancer who relapse after high-dose chemotherapy (HDC). Blood 94: 353a, 1999 (Abstract 1572) **(Presented as a poster at the 1999 American Society of Hematology meeting)**

Byrd JC, Grever MR, Davis B, Lucas MS, Park K, Goodrich A, Morrison C, Murphy T, Kunkel L, Grillo-Lopez A, Waselenko JK, Flinn IW. Phase I/II study of thrice weekly rituximab in chronic lymphocytic leukemia/small lymphocytic lymphoma: A feasible and active regimen. Blood 94: 704a, 1999 (Abstract 3114) **(Presented as an oral presentation at the 1999 American Society of Hematology meeting)**

Byrd JC, Willis CR, Waselenko JK, Park K, Goodrich A, Morrison C, Lucas MS, Shinn C, Diehl LF, Grever MR, Flinn IW. Theophylline, pentostatin, and chlorambucil: A dose escalation study to modulate intrinsic resistance mechanisms in patients with relapsed lymphoproliferative disorders. Blood 94: 308b, 1999 (Abstract 4602)

Myhand R., Waselenko J, Coleman T, Waddell JA, Caton J. Post-transplant relapse salvage chemotherapy with vinblastine, mitoxantrone, thiotepa, and halotestine (VMTH) in patients with metastatic breast cancer. Blood 94: 403b, 1999 (Abstract 5029)

Myhand R., Waselenko J, Lewis E, Reeb B, Babior B. Refrigerated stem cells stored in modified fluid gelatin (MFG) support durable engraftment in patients with breast cancer receiving high-dose chemotherapy (HDC). Blood 94: 359b, 1999 (Abstract 4831)

Myhand R., Coleman T, Atkins M., Waselenko J, Preston G, Vukelja S. Tandem transplant with melphalan is inferior to tandem transplant with cyclophosphamide, etoposide, etoposide, and carboplatin (CEC) in patients with metastatic breast cancer. (Proc Am Soc Clin Oncol 18: 63a, 1999 (Abstract 237)

Prieto R., Waselenko J.K., Johnson T.R., Olivere J.W., Natarajan S., Byrd J.C. Epstein barr virus (EBV) associated primary central nervous system lymphoma (PCNSL) arising in a patient after fludarabine and corticosteroid treatment. Blood 92: 228b, 1998 (Abstract 3980)

Byrd J.C., Waselenko J.K., Maneatis T.A., Ward F. T., Weickum R., White C.A. Rituximab therapy in hematologic malignancy patients with circulating blood tumors: Associated with increased infusion related side effects and rapid tumor lysis. Blood 92: 106a, 1998 (Abstract 432) **(Presented as a poster at the 1998 American Society of Hematology meeting)**

Myhand R, Vulkelja S, Coleman T, Waselenko J, Deleon M, Caton J. Infusional paclitaxel induces rapid liver transaminase elevations in patients with metastatic breast cancer receiving paclitaxel, cisplatin, and cyclophosphamide (PCC) with autologous peripheral blood stem cell support. Blood 92: 275a, 1998 (Abstract 1129) **(Presented as a poster at the 1998 American Society of Hematology meeting)**

Waselenko J.K., Grever M.R., Shinn C.A., Flinn I.W., Diehl L.F., Byrd J.C. Gemcitabine demonstrates significant in vitro activity in heavily pre-treated B-cell chronic lymphocytic leukemia (B-CLL). Blood 90: 310b, 1997. (Abstract 4148)

Waselenko J.K., Przygodzki R., Grever M.R., Shinn C.A., Byrd J.C. Flavopiridol, UCN-01 FR901228, and Gemcitabine have significant in *vitro* activity in *de novo* B-cell prolymphocytic leukemia with aberrant p53 function. Blood 90: 532a, 1997. (Abstract 2369)
(Presented as a poster at the 1997 American Society of Hematology meeting)

Waselenko J.K., Byrd J.C., Shinn C.A., Flinn I.W., Diehl L.F., Sausville E., Grever M.R. Flavopiridol has marked in vitro activity against the K-562 cell line and human acute leukemia cells. Blood 90: 249b, 1997. (Abstract 3858)

Waselenko J.K., Byrd J.C., Shinn C.A., Flinn I.W., Diehl L.F., Sausville E., Grever M.R. Carboxyamido-triazole (CAI), a signal transduction inhibitor, demonstrates marginal activity against human B-chronic lymphocytic leukemia *in vitro*. Blood 90: 310b, 1997. (Abstract 4147)

Byrd J.C., Waselenko J.K., Shinn C.A., Bedi A., Flinn I.W., Diehl L.F., Sausville E., Grever M.R. FR901228, a novel bicyclic depsipeptide, has significant in vitro activity against human B-chronic lymphocytic leukemia (B-CLL). Blood 90: 532a, 1997. (Abstract 2367)
(Presented as a poster at the 1997 American Society of Hematology meeting)

Byrd J.C., Waselenko J.K., Shinn C.A., Miller C., Gore S., Sausville E., Grever M.R. FR901228, a novel antitumor bicyclic depsipeptide, has marked in vitro activity in both the K-562 cell line and human acute leukemia cells. Blood 90: 238b, 1997. (Abstract 3810)

Byrd J.C., Shinn C.A., Bedi A., Waselenko J.K., Fuchs E, Flinn I.W., Diehl L.F., Sausville E., Grever M.R. Flavopiridol has marked in vitro activity against human B-chronic lymphocytic leukemia (B-CLL) and induces apoptosis independent of p53. Blood 90: 531a, 1997. (Abstract 2366) **(Presented as a poster at the 1997 American Society of Hematology meeting and at the 1997 American College of Physicians (ACP), Army Chapter meeting, Hematology Section)**

Byrd J.C., Shinn C.A., Bedi A., Waselenko J.K., Flinn I.W., Diehl L.F., Sausville E., Grever M.R. UCN-01: A promising new agent for B-cell chronic lymphocytic leukemia (B-CLL) that induces apoptosis independent of p53 status. Blood 90: 306b, 1997. (Abstract 4125)

Byrd J.C., Waselenko J.K., Shinn C.A., Flinn I.W., Diehl L.F., Grever M.R. Interleukin-4 induces resistance to F-ara-A and UCN-01 but not Flavopiridol in a BCL-2 independent manner. Blood 90: 532a, 1997. (Abstract 2368) **(Presented as a poster at the 1997 American Society of Hematology meeting)**

Shinn C.A., Byrd J.C., Waselenko J.K., Sausville E., Miller C., Gore S., Grever M.R. UCN-01 has significant in vitro activity in both the resistant K562 and human acute leukemia cells. Blood 90: 246b, 1997. (Abstract 3848)

Poster Presentations: Noted in abstract section.

B. Journal articles:

Weisdorf D, Chao N, Waselenko JK, Dainiak N, Armitage JO, McNiece I, Confer D. Acute radiation injury: contingency planning for triage, supportive care, and transplantation. Biol Blood Marrow Transplant. 12:672-82, 2006

Waselenko J.K., Flinn I.W., Reese A, Lucas M, Park K, Goodrich A, Shinn C.A., Willis C.R., Morrison C, Diehl LF, Grever M.R, Byrd J.C. A phase I/II study targeting intrinsic biologic resistance factors employing theophylline, pentostatin, and chlorambucil in patients with relapsed lymphoproliferative disorders. Ann Hematol. 85:301-7, 2006

Goans RE, Waselenko JK. Medical Management of Radiological Casualties, NCRP Annual Meeting 2004. Health Phys. 89:505-12, 2005

Jackson, WL jr., Gallagher C, Myhand RC, Waselenko JK. Medical Management of Multiple System Organ Dysfunction Arising in Patients with Acute Radiation Injury. BJR Suppl. 27:161-8, 2005

Waselenko JK, MacVittie TJ, Blakely WF, Pesik N, Wiley A, Dickerson WE, Tsu H, Confer DL, Coleman CN, Armitage JO, Dainiak N. Medical management of the acute radiation syndrome: recommendations of the Strategic National Stockpile Working Group. Ann Intern Med.140: 1037-1051, 2004

Belford AM, Myles O, Myhand RC, Wang J, Magill A, Waselenko JK. Thrombotic Microangiopathy (TMA) and Stroke Due to Human Herpesvirus-6 (HHV-6) Reactivation in an Adult Receiving High-dose Melphalan with Autologous Peripheral Stem Cell Transplantation. Am J Hematol76:156-162, 2004
Dainiak N., Waselenko, J.K, Armitage J.O., MacVittie T, Faress AM. The hematologist and radiation casualties. Hematology 2003 (Am Soc Hematol Ed Prog Book): 473-496.

Waselenko JK, Burrows A, Nelson DA, Lucas M, Ekstrand J, Edenfield WJ, Myhand RC. Post-transplant interleukin 2 (IL2) in patients with low-grade lymphoid neoplasms previously treated with fludarabine associated with increased hematologic toxicity. Ann Hematol. 82: 552-557, 2003

Waselenko J.K., Shinn C.A., Willis C.R., Flinn I.W., Grever M.R., Byrd J.C. Carboxyamido-triazole (CAI), a novel static signal transduction inhibitor induces apoptosis in human B-chronic lymphocytic leukemia cells. Leuk Lymphoma 42: 1049-1053, 2001

Byrd J.C., Murphy T., Howard R.S., Lucas M.S., Goodrich A., Park K., Pearson M., Buj V., Waselenko J.K., Ling G, Grever M., Kunkel L., Flinn I.W. Rituximab administered using a thrice weekly dosing schedule in B-cell chronic lymphocytic leukemia and small lymphocytic lymphoma demonstrates significant activity. J Clin Oncol 19: 2153-64, 2001

Waselenko J.K., Grever M.R., Shinn C.A., Flinn I.W., Byrd J.C. Gemcitabine demonstrates selective in vitro activity in human B-cell chronic lymphocytic leukemia. Leuk Res 25: 435-40, 2001

Byrd J.C., Waselenko J.K., Keating M., Rai K., Grever M.R. Novel therapies for chronic lymphocytic leukemia in the 21st century. Semin Oncol 27:587-597, 2000

Waselenko J.K., Grever M.R , Beer M, Lucas M,., Byrd J.C. Pentostatin (Nipent) and chlorambucil with GM-CSF support for patients with previously untreated, treated, and fludarabine-refractory B-cell chronic lymphocytic leukemia. Semin Oncol 27 (Suppl 5): 44-51, 2000

Byrd J.C., Grever, M.R., Waselenko J.K., Willis C.R. Park K, Goodrich A, Lucas M.A. Shinn C, Flinn I.W. Theophylline, pentostatin, (Nipent), and chlorambucil: A dose-escalation study targeting intrinsic biologic resistance mechanisms in patients with relapsed lymphoproliferative disorders. Semin Oncol 27 (Suppl 5): 37-40, 2000

Byrd J.C., Shinn C.A., Raji R., Willis C.R., Waselenko J.K., Flinn I.W., Dawson N.A., Grever M.R. Depsipeptide (FR901228): A novel therapeutic agent with selective, *in vitro* activity against human B-chronic lymphocytic leukemia cells. Blood 94: 1401-8, 1999

Byrd J.C., Waselenko J.K., Maneatis T.A., Ward F. T., Weickum R., White C.A. Rituximab therapy in hematologic malignancy patients with circulating blood tumors: An association with increased infusion related side effects and rapid tumor lysis. J Clin Oncol 17: 791-795, 1999

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Waselenko J.K., Nace M.C., Alving B.A. Women with thrombophilia: Assessing the risks for thrombosis with oral contraceptives or hormone replacement therapy. Seminars in Thrombosis and Haemostasis 24 (Suppl 1): 33-39, 1998

Tuttle R.M., Waselenko J.K., Yoseffi P, Weigand N, Martin R.K. Preservation of nucleic acids for PCR after prolonged storage at room temperature.Diagn Mol Pathol 7: 302-9, 1998.
Waselenko J.K., Flynn J.M., Byrd J.C. Stem cell transplantation in chronic lymphocytic leukemia: The time to design randomized studies has arrived. Semin Oncol 26: 48-61, 1998

Kenner J.R., Sperling L.C., Waselenko J., Dawson N., Sau P., Moul J.W. Suramin Keratosis: A unique skin eruption in a patient receiving suramin for metastatic prostate cancer. J Urol 158: 2245-2246, 1997.

Waselenko J.K., Dawson N.A. Management of Progressive Metastatic Prostate Cancer. Oncology 11:1551-60, 1997.

D. Continuing Medical Education Contributions
Rush University/USUHS CME Module: Bioterrorism Preparedness Series: Medical Management of a Victim of a Radiological Dispersal Device "Dirty Bomb". Waselenko JK, Goans, RE.

UpToDate:
I. Dainiak N, Waselenko JK. Biology and clinical features of radiation injury in adults
II.Waselenko JK, Armitage JO, Dainiak N. Treatment of radiation injury in the adult

Teaching Experience
Supervisory Teaching-

Direct Supervision
Medical Students
Internal Medicine Preceptor, Wilford Hall Medical Center, May-June 1999.
Internal Medicine Attending, Walter Reed Army Medical Center, July-August 2001
ICM III-Physical Exam Preceptor March-April 2002
Internal Medicine Clerkship Preceptor September-October 2002
ICM III-Physical Exam Sim. Center Jan.-Feb. 2004
ICM III-Physical Exam Sim. Center Feb-March 2004

Residents and Fellows
Internal Medicine Outpatient Clinic Preceptor (Hematology/Oncology Clinic), Walter Reed Army Medical Center, November 2001.
Internal Medicine Outpatient Clinic Preceptor (Hematology/Oncology Clinic), Walter Reed Army Medical Center, Feb-March 2002.

Walter Reed Army Medical Center, Fellow's Clinic Mentor:
Dr Jasmine Daniels (July-August 2001)
Dr Edward Gorak (August –November 2001)
Dr Jeremy Perkins (February 2002-March 2002)
Dr Amy Belford (April 2002-June 2002)
Dr Jennifer Crook (Sept. 2002-December 2002)
Dr Brendan Weiss (Jan 03-June 2003)
Dr Jeremy Perkins (Jan 03-June 2003)
Dr Tanya Morgan (July 03-December 2003)
Dr David Van Echo (July 03-December 2003)
Dr Christopher Gallagher (Jan. 2004-April 2004)

Dr. Colleen McGettigan (Jan. 2004-June 2004)
Dr. Gauri Alvarez (March 2004-June 2004)

Brooke Army Medical Center, Fellow's Clinic Mentor:
Dr. Douglas Nelson (July 1999-December 1999; July 2000-December 2000)
Dr. Samuel Wood (January 2000-June 2000; January 2001-March 2001)
Dr. Garry Schwartz (January 1999-June 1999)
Dr. Patrick Williams (July 1998-December 1998)

Conferences, Lectures, and Symposia

National or International Conferences/Symposia:
Invited Lecturer, ASCO Investigator's Meeting, Atlanta, GA, May 1999. **"A phase II multicenter study of pentostatin and chlorambucil with cytokine support in patients with previously untreated, treated, and fludarabine-refractory chronic lymphocytic leukemia (CLL)"**

Invited Lecturer, Advanced Research Workshop on "Radiation-Induced Multi-Organ Involvement and Failure: A Challenge for Pathogenic, Diagnostic, and Therapeutic Approaches and Research" at the Science Conference Center Schloss Reisenburg of the University of Ulm, November 15, 2003. **"Medical Approach to Therapy of the Radiation Victim with Combined Injuries and Multiple Organ Dysfunction"**

Invited Lecturer, Radiation and the Hematologist, Education Session, 6&7 December 2003, San Diego, CA. **"Medical Management of the Hematopoietic Syndrome"**

Invited Lecturer,. American Society of Clinical Oncology Annual Meeting, Chicago, IL. Expert opinion session, 2&3 June 2003, on **"Hematologic Consequences of Nuclear Terrorism"**

Invited Lecturer, Interorganizational Meeting on Radiological/Nuclear Mass Casualty Preparedness, ASH, San Diego, CA, 6 December 2004. **"Medical Management of Mass Radiological Casualties with Hematopoietic Syndrome Consequent to Nuclear Terrorism"**

Invited Lecturer, ASBMT/CIBMTR, Tandem Transplant Meeting, Concurrent session on NMDP contingency planning for the community, Keystone, CO, 10 February 2005. **"Acute Radiation Syndrome: The Role of the Transplant Physician"**

Invited Lecturer, AABB Audioconference: Contingency Planning-Protocol for the Management of Radiation Victims, 29 March 2006. **"Radiation Injury Consequent to Nuclear Terrorism"**

Invited Lecturer, AABB Annual Meeting, Radiation Injury and Countermeasures, Miami, FL. 24 October 2006 – **"Health Care Response to a Radiation Incident: A Nation's Challenge"**

Invited Lecturer, Radiation Research Society Annual Meeting, Philadelphia, PA. 5-6 November 2006 – **"Medical Management Of Hematopoietic Syndrome: A Nation's Challenge"**

Seminar Invitations:

Invited Lecturer, 1999 Rituxan Investigator's Meeting, Seattle, WA, August 1999. **"Rituxan in Hematologic Malignancy with Circulating Blood Tumor Cells."**

Invited Lecturer, 2000 Supergen Advisory Meeting, Scottsdale, AZ, January 14, 2000. **"N816: A phase II multicenter study of pentostatin and chlorambucil with cytokine support in patients with previously untreated, treated, and fludarabine-refractory chronic lymphocytic leukemia (CLL): January 2000 Update."**

Invited Lecturer, Texas Oncology Protocol Meeting, Dallas, TX, May 9, 2000. **" Chronic Lymphocytic Leukemia: The Quest for Survival Prolongation."**

Invited Lecturer, 2000 Supergen Advisory Meeting, Laguna Beach, CA, August 11, 2000 **" A phase II multicenter study of pentostatin and chlorambucil with cytokine support in patients with previously untreated, treated, and fludarabine-refractory chronic lymphocytic leukemia (CLL): N816 Update."**

Invited Lecturer, Sammons Cancer Center, Baylor University, September 14, 2000. **" Chronic Lymphocytic Leukemia: The Quest for Survival Prolongation."**

Invited Lecturer, U.S. Oncology Network educational meeting, titled **"Recent Advances in the treatment of leukemias, lymphomas, and other hematological malignancies", Phoenix, AZ, October 21, 2000.** "Purine Analogue Combinations in Chronic Lymphocytic Leukemia: A Historical Perspective."

Invited Lecturer, Strategic National Stockpile Working Group Conference, III, January 22, 2003. **"The role of cytokines in treatment-related neutropenia."** AFRRI, Bethesda, MD

Invited Lecturer, Strategic National Stockpile Working Group Conference, IV. May 14, 2003. **"Arriving at a treatment consensus for patients with acute radiation syndrome (ARS)- An overview and working group discussion."** AFRRI, Bethesda, MD

Invited Lecturer, Strategic National Stockpile Working Group *subcommittee meeting* on the medical management of high-risk neutropenia in adults and children arising from acute radiation syndrome AFRRI, Bethesda, MD, 23 February 2005. **"Hematopoietic Syndrome Consequent to Nuclear Terrorism: Rationale and Recommendations by Strategic National Stockpile Working Group"**

Keynote Speaker, Responding to Hematologic Toxicity from a Nuclear Detonation Event, Memorial Sloan Kettering, 28 April 2006. **"Medical Management of Acute Radiation Syndrome"**

Institutional Educational Lectures(including Grand Rounds):

Invited Lecturer, Brooke Army Medical Center, Internal Medicine Conference, December 1998. **"Hematopoietic Stem Cell Transplantation."**

Invited Lecturer, Brooke Army Medical Center, Fellow Conference, June 1999. **"Thalassemia Syndromes 101: Back to The Basics."**

Invited Lecturer, Brooke Army Medical Center, Internal Medicine Conference, December 2000. **"Hematopoietic Stem Cell Transplantation: A Primer."**

Invited Lecturer, Walter Reed Army Medical Center. Fellow's Morning Conference, September 20, 2002. **"Hematopoietic Stem Cell Transplantation: An Overview and Orientation."**
Invited Lecturer, Walter Reed Army Medical Center, internal medicine resident's noon conference, March 20, 2003. **"On oncologic emergencies: The role of the internist".**

Invited Lecturer,. Walter Reed Army Medical Center Grand Rounds, September 12, 2003. **"Hematologic Consequences of Acute Radiation: Medical Management Proposed by the Strategic National Stockpile Working Group"**

Invited Lecturer, Armed Forces Radiology Research Institute/USUHS Medical Effects of Ionizing Radiation course, 4 August 2004. **"Medical Management of the Hematopoietic Syndrome"**

Invited Lecturer, Centennial Medical Center Nursing Conference, 7 September 2005, **"Acute Myelogenous Leukemia Management."**

Invited Lecturer, Tennessee Oncology Education Conference, 7 February 2006. **"The Role of Stem Cell Transplantation in the Management of Acute Myelogenous Leukemia in First Complete Remission"**

Invited Lecturer, The Christ Hospital, Resident's Conference, March 2008, September 2008, March 2010, March 2011 **"Paraneoplastic Syndromes"**

Invited Lecturer, The Christ Hospital, Resident's Conference, November 2009, October 2014. **"A Practical Approach to Anemia"**

Invited Lecturer, The Christ Hospital, Resident's Conference, May 2013. **"Management of Acute Leukemia"**

Invited Lecturer, The Christ Hospital, Resident's Conference, October 2013. **"Lymphadenopathy: When to wait and when to refer"**

Presentations at State or Local Conferences:
Invited Lecturer, City-Wide Bone Marrow Transplant Conference, Brooke Army Medical Center, January 28, 1999. **"The Optimal Timing of And The Role of Colony Stimulating Factors in The Restoration of Hematopoiesis Post-Transplant."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, Brooke Army Medical Center, February 28, 1999. **"Battle Strategies in Critically Ill Stem Cell Transplant Patients: Knowing When to Retreat."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, Brooke Army Medical Center, July 22, 1999. **"Campath 1H Antibodies: An Overview And Update of Its Role in Stem Cell Transplantation."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, University of Texas at San

Antonio, November 18, 1999. **"Post-transplant relapse survival and subsequent therapy in patients with breast cancer ."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, University of Texas at San Antonio, January 20, 2000. **"IL-2 After Autologous Stem Cell Transplant in Low-Grade Lymphoma."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, University of Texas at San Antonio, March 2, 2000. **"Primary refractory myeloma: Evidence based management in high-dose chemotherapy."**

Invited Lecturer, City-Wide Bone Marrow Transplant Conference, University of Texas at San Antonio, October 19, 2000. **"An Update on Mucosal Barrier Injury Encountered in High-Dose Chemotherapy And Its Management."**

Invited Lecturer, Oncology Grand Rounds, University of Nebraska, February 2000. **"Chronic Lymphocytic Leukemia: Where are we going? Where have we been?"**

Invited Lecturer, Rush Presbyterian, Chicago, IL. Noon Conference, October 17, 2001. **"Hematologic Complications Encountered in Chronic Lymphocytic Leukemia: An Overview"**

Invited Lecturer, Cook County Hospital, Chicago IL. Noon Conference October 18, 2001. **"Purine Analogue Combinations in CLL: Important Treatment Advances"**

Invited Lecturer, University of Illinois, Hematology Conference, October 18, 2001. **"Hematologic Complications Encountered in Chronic Lymphocytic Leukemia: An Overview"**

Invited Lecturer, University of Connecticut University Health Center, Farmington, CT, 10 August 2004. *Radiation and Preparedness for the Public Health and Hospital Workforce* Workshop, **"Management of Victims of a Mass Casualty Radiation Event."**

Invited Lecturer, Suburban Hospital, Bethesda, MD, Grand Rounds, 12 November 2004. **"Medical Management of the Hematopoietic Syndrome"**

Invited Lecturer, U.S. Food and Drug Administration, Office of Counter-Terrorism, Rockville, MD, 15 November 2004. **"Medical Management of the Hematopoietic Syndrome Consequent to Nuclear Terrorism"**

Invited Lecturer, Holy Name Hospital, Teaneck, NJ, Grand Rounds, 30 November 2004. **"Recent Advances in Clinical Aspects and Treatment of Chronic Lymphocytic Leukemia."**

Invited Lecturer, Annual Tri-State Chapter Blood Cancer Conference- Leukemia Lymphoma Society, Great Wolf Lodge, Mason, OH, April 2014. **"Treatment Updates in Hodgkin's Lymphoma."**

Invited Lecturer, Annual Tri-State Chapter Blood Cancer Conference- Leukemia Lymphoma Society, March 14, 2015. **"Treatment Update In Leukemia."**

EXHIBIT 7

AFFIDAVIT

Addendum 1

State of Ohio

County of Clermont

I, Jamie Kendrick Waselenko, MD, of 1773 Clough Pike, Batavia, OH 45103, after being duly sworn in, do hereby swear under oath that:

1. My training, my life's work, and 29 years of experience as a medical doctor justifies my position and ability to serve as an expert witness for this issue.

Firstly, I graduated from an American medical school in 1992. While in medical school, I received training in critical analysis of medical literature, infectious diseases, epidemiology, microbiology including virology, immunology and general medicine. I went on to further sub-specialize in internal medicine, hematology, and oncology for which I am board certified. My background also includes a year of preclinical research performed at Johns Hopkins University in Baltimore, Maryland. Research and the critical analysis of medical literature are foundational in my training.

Moreover, by virtue of being a hematologist and oncologist, I have subspecialty expertise in the management of patients with immunodeficiencies, low blood counts, blood clot disorders, as well as the management of both benign and malignant hematologic diseases and solid tumor oncology. The field of oncology has rapidly changed over the last 20 years. The advent of immune-based therapies as well as the introduction of PDL-1 antibody-based therapy has led to most oncologists acquiring expertise in immuno-oncology. I am also trained in the field of bone marrow transplantation. This background confirms my ability to take care of complex patients with immune deficiencies, autoimmune complications of their treatment and/or disease, as well adverse drug reactions associated with chemotherapy and/or immunotherapy.

The introduction of this novel technology (COVID-19 gene-based vaccine) never used in humans and the sudden push to use in patients without any long-term safety data or preclinical animal data gave me great concern. Because of this, I began an extensive search and continue to critically examine all data as it pertains to COVID-19 and COVID-19 gene-based therapy vaccination. During this time, I also began to take care of many patients with COVID-19 associated hematologic complications and some with COVID-19 vaccine induced toxicities.

The COVID-19 spike protein, whether it is due to the virus or the vaccine, is thrombogenic (blood clot inciting). In fact, COVID-19 infection and the COVID-19 gene-based vaccines have both been implicated in micro-vascular and macrovascular thrombotic complications. Among these complications are pulmonary emboli, deep vein thrombosis, and arterial thrombotic events like ischemic stroke and myocardial infarction. COVID-19 is a multisystem disease where many vascular and hematologic complications arise, often prompting hematology

consultation. These COVID-19 induced hematologic complications include virus induced lymphopenia, neutrophilia, thrombotic microangiopathy, the development of antiphospholipid antibodies, macrophage activation syndrome, thrombocytopenia, coagulopathy, in addition to the thrombotic complications previously mentioned. Studies have shown a significant link between COVID-19 viral injury and vascular dysfunction.

The critical examination of the literature, the participation and experience in the care of patients with COVID-19 induced multi-system organ dysfunction, as well as hematologic complications due to COVID-19 infections, has led to my expertise in this area.

2. My arguments are based on science, not conspiracy theories. This accusation is often used to discredit or disqualify discourse. The facts speak for themselves. My comments in my original attestation acknowledge multiple sources, and I am happy to offer formal sources and references for each of my points.

3. Updates from the CDC website on the COVID-19 infection fatality rate as of 8/25/2021 continues to show that the COVID-19 viral induced mortality in the young is extremely low and cannot justify mandating a mass vaccination with a novel gene-based therapy with no pre-clinical data or long-term safety data.

4. In terms of the safety arguments, my comments are simply, look at the data. Refer to the Vaccine Adverse Event Reporting system-VAERS website. This will show you the acute toxicity data being reported in associated with COVID-19 gene-based therapies, realizing this likely reflects 1% of what has really been experienced based on the Harvard 2009 study I previously quoted. The toxicity of these gene therapy-based vaccines is unprecedented, emphasis added. These vaccine induced injuries are leading to significant multi-organ complications, disability, and death. Long-term toxicity data is not available and will likely amass over the next 10-20 years. I say again, the "cure" should not be worse that the disease.

5. Additional relevant data continues to evolve. Several important updates follow. Not surprisingly, recent data has shown that increased viral load increases infection rates. In the Lancet Infection Diseases Journal in May 2021, the investigators demonstrated that the viral load was a leading driver for COVID-19 infectivity and transmission (a). This is an extremely important and relevant issue. See 6.

6. An important study was published in August 2021 in the Lancet (b). This study looked at the viral load in the nose and mouth of healthcare workers before and after vaccines were implemented. They found that the viral load of the COVID-19 Delta variant was 251 times higher than what they saw prior to their healthcare workers being vaccinated. While there may be many criticisms of this study, it is unclear if healthcare workers may be at higher risk of carrying a higher viral load, which has been linked to higher infectivity. This may mean that vaccinated healthcare workers may not only generate COVID-19 mutants, but that they are at higher risk of spreading the virus to their families, co-workers, and patients. This should give everyone pause until we know more.

7. Israeli data published in August 2021 has shown that natural immunity confers longer lasting and stronger protection against infection, symptomatic disease, and hospitalization caused by the

delta variant of COVID-19 compared to the BNT162b2 COVID-19 gene-based vaccine induced immunity. Their analysis demonstrates that COVID-19 gene-based therapy vaccinees had a 13-fold increased risk for breakthrough infection with the Delta variant compared to those who had been previously infected and developed natural immunity(c) Moreover, natural immunity does not lead to the acute and long-term risk of unnecessary COVID-19 gene-based vaccination injury and appears to protect against the Delta variant.

REFERENCES:

a. Marks M, Millat-Martinez P, Ouchi D, h Roberts C, Alemany A, Corbacho-Monné M, Ubals M, Tobias A, Tebé C, Ballana E, Bassat Q. Transmission of COVID-19 in 282 clusters in Catalonia, Spain: a cohort study. The Lancet Infectious Diseases. 2021 May 1;21(5):629-36.

b. Chau NV, Ngoc NM, Nguyet LA, Quang VM, Ny NT, Khoa DB, Phong NT, Toan LM, Hong NT, Tuyen NT, Phat VV. Transmission of SARS-CoV-2 Delta Variant Among Vaccinated Healthcare Workers in Vietnam.

c. https://www.medrxiv.org/content/10.1101/2021.08.24.21262415v1.full.pdf

Under penalty of perjury, I hereby declare and affirm that the above stated facts, to the best of my knowledge, are true and correct, and I reserve the right to supplement my opinion. I present my opinions based on a reasonable degree of medical certainty. I give these opinions based on my attached curriculum vitae, my education, my work history, my experience and a review of all the scientific data.

DATED this 30th day of August, 2021

Signature

JAMIE K. WASELENKO

Printed Name

NOTARY ACKNOWLEDGMENT

State of Ohio)

) **(Seal)**

County of Vermont)

The foregoing instrument was acknowledged before me this 30th day of August, 2021, by the undersigned, Jamie Waselenko, who is personally known to me or satisfactorily proven to me to be the person whose name is subscribed to the within instrument.

Signature

Shellie Kay Seip

Notary Public

My Commission Expires: 8/7/2022

NOTARY PUBLIC STATE OF OHIO

SHELLIE KAY SEIP
Notary Public, State of Ohio
My Commission Expires
August 7, 2022

EXHIBIT 8

United States Senate
WASHINGTON, DC 20510

August 26, 2021

Janet Woodcock, M.D.
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Acting Commissioner Woodcock:

On August 23, 2021, the FDA reissued the Emergency Use Authorization (EUA) for the Pfizer-BioNTech COVID-19 vaccine.[1] This vaccine is currently available and used in the United States. At the same time, the FDA announced its approval of the biologics license application submitted by BioNTech Manufacturing GmbH for Comirnaty (COVID-19 Vaccine, mRNA) against COVID-19 for individuals 16 years of age and older.[2] According to the FDA, "there is not sufficient approved vaccine [Comirnaty] available for distribution" in the U.S.[3]

In the letter that reissued the EUA for the Pfizer-BioNTech COVID-19 vaccine, the FDA stated that Comirnaty and the Pfizer-BioNTech COVID-19 vaccines are "legally distinct with certain differences that do not impact safety or effectiveness."[4] That statement, together with the fact that the FDA issued two distinct letters – one extending the EUA for the vaccine used in the U.S. and the other granting the FDA approval of the Comirnaty vaccine used in Europe and other countries – has caused a great deal of confusion.

As I stated to you in my letter dated August 22, 2021, "I see no need to rush the FDA approval process for any of the three COVID-19 vaccines. Expediting the process appears to only serve the political purpose of imposing and enforcing vaccine mandates."[5] Because the FDA-approved Comirnaty vaccine is not generally available in the U.S., but the Pfizer-BioNTech COVID-19 vaccine will continue to be used in the U.S. under a reissued EUA, the FDA seems to be confirming my suspicion.

[1] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download.
[2] Letter to Amit Patel, BioNTech Manufacturing GmbH, from Mary Malarkey, Director, Office of Compliance and Biologics Quality, U.S. Food and Drug Administration, and Marion Gruber, Director, Office of Vaccines Research and Review, U.S. Food and Drug Administration, Aug. 23, 2021 available at https://www.fda.gov/media/151710/download.
[3] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download (See footnote 9).
[4] *Id.* at 2 (See footnote 8).
[5] Letter from Ron Johnson, U.S. Senator, to Janet Woodcock, Acting Commissioner, U.S. Food and Drug Administration, et al., Aug. 22, 2021.

In order to address the confusion created by the FDA's August 23, 2021 letters, I am asking that you expeditiously provide answers to the following questions:

1) Why didn't the FDA grant full licensure for the Pfizer-BioNTech vaccine that is in use and available in the U.S.?

2) How are the Comirnaty and Pfizer-BioNTech COVID-19 vaccines "legally distinct" and what are the "certain differences"?

3) There is no doubt that the FDA's action will lead to more vaccine mandates and increased pressure on those currently choosing not to get vaccinated. Your letter to Pfizer suggests that "there is not sufficient approved vaccine available for distribution."[6] Is there sufficient supply in the U.S. of the Comirnaty vaccine to ensure that those being vaccinated under mandates will be receiving the FDA-approved version? Or is it more likely (or certain) that they will be vaccinated using the vaccine administered under the reissued EUA?

4) If there is insufficient supply of Comirnaty vaccines for those succumbing to the coercion of mandates, isn't the FDA *de facto* endorsing vaccine mandates utilizing EUA vaccines?

5) Will individuals who receive either vaccine be afforded the same legal protections if they are injured by the vaccine? If not, why not?

I look forward to receiving a response to this limited number of questions no later than August 30, 2021. Your answers are crucial to Americans who will now be forced into making potentially life-altering decisions in response to the employer, military and educational mandates that your August 23, 2021 letters have triggered. I will also be sending you a more detailed follow-up letter to your inadequate response to my August 22, 2021 letter in the next few days.

Sincerely,

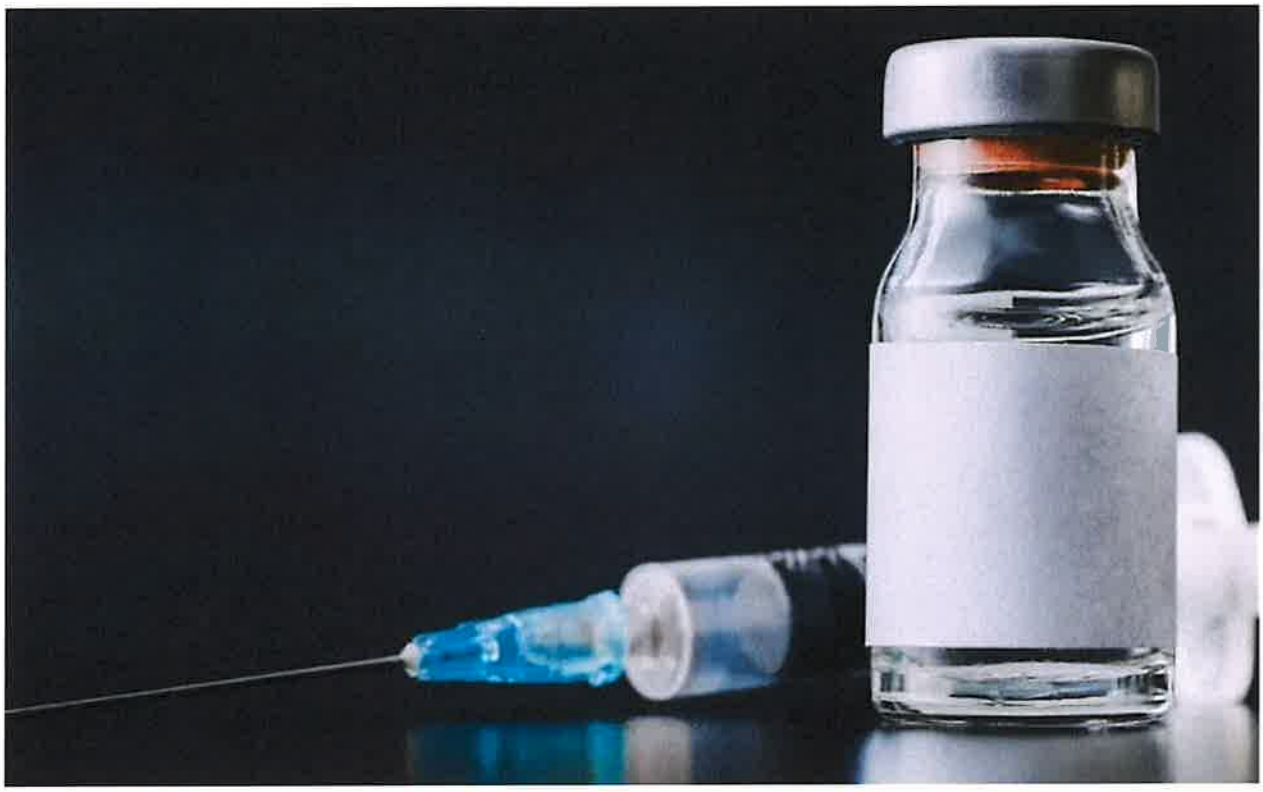
Ron Johnson
U.S. Senator

[6] Letter to Elisa Harkins, Pfizer Inc., from Denise Hinton, Chief Scientist, U.S. Food and Drug Administration at 5, Aug. 23, 2021 available at https://www.fda.gov/media/150386/download (See footnote 9).

EXHIBIT 9

LeoHohmann.com

Investigative reporting on globalism, Christianity, Islam, Judaism and where politics, culture and religion intersect



BOOM! Major law firm confirms FDA deceived America with its confusing 'approval' of Pfizer vax

When the U.S. Food and Drug Administration announced Aug. 23 it had granted full approval to the first Covid "vaccine" under the brand name Comirnaty, the mainstream media immediately ran with the narrative.

Joe Biden jumped in front of a microphone and told businesses they needed to "step up" the mandating of vaccines for their employees.

Dr. Anthony Fauci told national media outlets he expected a whole host of new "mandates" to be fueled by the "approval" of the Pfizer jab.

There's only one problem. The "approval" given by the FDA was not for the Pfizer jab currently available in the U.S. market.

The devil is always in the details. Some of us weren't fooled.

See our article, which has over the past three days received nearly 150,000 reads: **FDA 'playing bait and switch' with Americans, tricking them into believing shots currently being offered have been granted full approval when they have not.**

But because we and a few others looked beneath the facade and checked the facts of what the FDA actually did and not what the media and Joe Biden's administration said it did, we took some heat. Even some of our own subscribers questioned whether maybe we got it wrong.

No, it was the corporate media who got the story wrong. And as a result, thousands of Americans no doubt capitulated and went ahead and rolled up theirs sleeves, thinking they had no other choice legally than to succumb to their employers' mandates.

Today, on Aug. 27, the Orlando, Florida-based Liberty Counsel, perhaps the most respected Christian legal firm in the nation, issued a **press release** that confirms our story.

Below is the release, published in full from Liberty Counsel.

WASHINGTON, D.C. – The Food and Drug Administration (FDA) has done a bait and switch by announcing it approved its "first COVID-19 vaccine" in order to push the "vaccine" mandates and protect the Pfizer pharmaceutical company from legal liability. However, there is currently no fully licensed COVID shot on the United States market.

Albeit confusing, and probably intentionally so, this summarizes the current status of the Pfizer-BioNTech shots:

1. All existing Pfizer vials (in the hundreds of millions), remain under the federal Emergency Use Authorization (EUA) (meaning people have the "option to accept or refuse");
2. The third or "booster" Pfizer shot is identical to the above and remains under the EUA with limited use to certain categories of people;
3. BioNTech received FDA approval for people ages 16 and above under the name Comirnaty, but there are no Comirnaty doses available in the United States;

4. **In other words, there is currently NO FDA approved COVID-19 injection available anywhere in the United States**. Every COVID shot in America remains under the EUA law and thus people have the "option to accept or refuse" them; and
5. Even when an FDA approved COVID shot becomes available, individuals are protected by federal law and many states laws from being forced to get these shots based on their sincere religious beliefs or conscience rights.

On August 23, the FDA issued two separate letters for two separate injections. There are now two legally distinct (Pfizer vs. BioNTech), but otherwise identical products.

The first letter is regarding FDA's biologics license application approval for the Pfizer Inc/BioNTech COVID-19 injection which has been named Comirnaty. Yet Pfizer has not started manufacturing or labeling this drug for U.S. distribution, so it is not even available in the U.S. It is unclear whether or not it is protected by a liability shield, but web-based U.S. government communication indicates that the same program that provides compensation for COVID vaccine-related injuries will apply Countermeasures Injury Compensation Program (CICP) rather than the National Vaccine Injury Compensation Program). At this point, there apparently has been no compensation paid to people injured by one of the COVID shots via the CICP.

The Pfizer injection, on the other hand, is still considered experimental under U.S. law. There is a legal difference between products approved under authorization of emergency use (EAU) compared with those the FDA has fully licensed. The FDA issued another letter for the existing Pfizer shots which confirms they are still under EUA, are not fully approved, and has a liability shield.

EUA-approved COVID shots have a liability shield under the 2005 Public Readiness and Preparedness Act. Vaccine manufacturers, distributors, providers and government planners are immune from liability. People who have been injured can file a lawsuit if they can prove willful misconduct, and if the U.S. government has also brought an enforcement action against the party for willful misconduct. No such lawsuit has ever succeeded.

That means people must be told the risks and benefits, and they have the right to decline a medication that is not fully licensed. The federal Emergency Use Authorization law and the FDA, including the FDA Fact Sheet, state unequivocally that each person has the "option to accept or refuse" the shots. In addition to federal law, the FDA includes the Nuremberg Code and the Helsinki Declaration on its website, emphasizing the fact that people cannot be forced to take experimental drugs without their full consent.

The FDA's approval letter to Pfizer regarding the BioNTech injection, Comirnaty, states: "Under this license, you are authorized to manufacture the product, COVID-19 Vaccine, mRNA, which is indicated for active immunization to prevent coronavirus disease 2019 (COVID-19) caused by severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) in individuals 16 years of age and older."

This letter affirms the FDA has not approved the Pfizer/BioNTech injections for the 12- to 15-year age group, nor any booster doses for anyone.

Regarding the Comirnaty injection, the FDA admits, "We have determined that an analysis of spontaneous post marketing adverse events reported under section 505(k)(1) of the FDCA will not be sufficient to assess known serious risks of myocarditis and pericarditis and identify an unexpected serious risk of subclinical myocarditis."

Therefore, follow up studies will be required with children six months to 15 years as well as six studies for up to five years regarding the adverse effects of myocarditis and pericarditis.

In addition, the FDA bypassed and disregarded the normal advisory committee and public comment process for this license.

The letter states, "We did not refer your application to the Vaccines and Related Biological Products Advisory Committee because our review of information submitted in your BLA, including the clinical study design and trial results, ***did not raise concerns or controversial issues that would have benefited from an advisory committee discussion***" (emphasis added).

The FDA also acknowledges that while Pfizer-BioNTech has "insufficient supplies" (in other words, it is not currently available on the U.S. market) of the newly licensed Comirnaty vaccine actually available. However, **the letter also states there is "a significant amount" of the Pfizer-BioNTech shots which has been produced under the EUA and will continue to be offered under the same EUA status. In its approval letter, the FDA specifies the Pfizer shot under the EUA should remain unlicensed, is still available for use, and can be used "interchangeably" with the newly licensed Comirnaty product.** According to the FDA, the newly licensed Comirnaty injection and the existing Pfizer shot, while "legally distinct," are not any different in terms of their "safety or effectiveness."

Despite whether these COVID shots are licensed or not, they cannot be mandatory under Title VII. In general, employee vaccine religious exemption requests must be accommodated, where a reasonable accommodation exists without undue hardship to the employer,

pursuant to Title VII of the Civil Rights Act of 1964. Many people hold sincere religious beliefs against taking the COVID shots or taking those derived from or which used at any stage of the development aborted fetal cell lines.

Title VII defines the protected category of religion to include "all aspects of religious observance and practice, as well as belief." 42 U.S.C. § 2000e(j). Moreover, as the EEOC has made clear, Title VII's protections also extend nonreligious beliefs if related to morality, ultimate ideas about life, purpose, and death. See EEOC, Questions and Answers: Religious Discrimination in the Workplace (June 7, 2008), ("Title VII's protections also extend to those who are discriminated against or need accommodation because they profess no religious beliefs...Religious beliefs include theistic beliefs, i.e. those that include a belief in God as well as non-theistic 'moral or ethical beliefs as to what is right and wrong which are sincerely held with the strength of traditional religious views.' Although courts generally resolve doubts about particular beliefs in favor of finding that they are religious, beliefs are not protected merely because they are strongly held. Rather, religion typically concerns 'ultimate ideas' about 'life, purpose, and death'").

Liberty Counsel Founder and Chairman Mat Staver said, "The FDA has apparently tried to deceive people by issuing its two confusing letters without proper explanation. Despite the FDA's slight of hand, there is currently no FDA approved COVID shot available in the United States. Even if there were an FDA approved COVID shot available, people still may request that employers, schools, and the military accommodate their sincerely held religious beliefs."

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May 2021

Memo on COVID Vaccination Mandates

Liberty Counsel is a national nonprofit litigation, education and public policy organization advancing religious freedom, the sanctity of human life, and family. We have engaged in extensive litigation regarding civil rights violations ostensibly justified by "COVID-19." We have had great success on behalf of our many clients at circuit courts of appeal and at the United States Supreme Court. *See, e.g., Harvest Rock Church v. Newsom*, No. 20A137, 2021 WL 406257 (U.S. Feb. 5, 2021); *Harvest Rock Church v. Newsom, Gov. of CA*, No. 20A94, 2020 WL 7061630 (U.S. Dec. 3, 2020); *Elim Romanian Pentecostal Church v. Pritzker,* 962 F.3d 341 (7th Cir. 2020); *Maryville Baptist Church, Inc. v. Beshear*, 957 F.3d 610 (6th Cir. 2020). The existence of COVID-19 does not justify the numerous violations of fundamental individual, economic and religious liberties. These include the rights of personal autonomy and bodily integrity, and the right to accept or reject the various COVID vaccines based on religious belief or other grounds.

COVID Vaccines Cannot Be Mandatory Under Emergency Use Authorization

On the issue of the COVID vaccines: all of such have been released under an Emergency Use Authorization ("EUA") and employers (religious and non-religious alike) may not condition continued employment on taking an EUA-authorized COVID vaccine.

The COVID vaccines are in a special category and cannot be treated like FDA licensed vaccines. None of the COVID vaccines are FDA licensed; nor have they received full FDA approval. Rather, their approval is under the special provision noted above as EUA. This means that there is not enough data (which includes duration of testing) for the FDA to render a final approval. More importantly, no one, including private employers, may coerce individuals (by threatening their employment or otherwise) to take an EUA vaccine. Federal law requires full and informed, voluntary consent.

All employees – whether employed by religious organizations, or not – are protected against mandated COVID-19 vaccines, under 21 U.S.C. §360bbb-3, which provides that EUA products (like all of these vaccines) require (as a condition of emergency approval) that **people have "the option to accept or refuse administration of the product.**" "FDA has an obligation to ensure that recipients of the vaccine under an EUA are informed… that **they have the option to accept or refuse the vaccine.**"[1] (emphasis added). There is no exception in the statute for "private employers" as opposed to government; or for religious or non-religious employers. All EUA vaccines are optional.

[1] https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

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Moreover, at the Centers for Disease Control Advisory Committee on Immunization Practices (ACIP) meeting held in August 2020, CDC-ACIP Executive Secretary Amanda Cohn, MD confirmed the non-mandatory nature of an EUA vaccine: "**under an Emergency Use Authorization, an EUA, *vaccines are not allowed to be mandatory***. So, early in this vaccination phase, individuals will have to be consented and they won't be able to be mandated." (emphasis added).[2]

COVID Vaccines Cannot Be Mandatory Under Title VII

In general, employee vaccine religious exemption requests must be accommodated, where a reasonable accommodation exists without undue hardship to the employer, under Title VII of the Civil Rights Act of 1964.

Many people hold sincere religious beliefs against taking any vaccines, or taking those derived from aborted fetal cell lines, or taking those sold by companies that profit from the sale of vaccines and other products derived from abortion.

Title VII, as amended, prohibits two categories of employment practices. It is unlawful for an employer: "(1) to fail or refuse to hire or to **discharge any individual, or otherwise to discriminate against any individual with respect to his compensation, terms, conditions, or privileges of employment**, because of such individual's race, color, **religion**, sex, or national origin; or (2) to limit, segregate, or classify his employees or applicants for employment in any way which would deprive or tend to deprive any individual of employment opportunities **or otherwise adversely affect his status** as an employee, because of such individual's race, color, **religion**, sex, or national origin." 42 U.S.C. § 2000e–2(a). (Emphasis added).

By pattern and practice, virtually every employer in America has shown that reasonable accommodations and alternatives to vaccination indeed exist for employees, and these have been required all along since the inception of COVID: self-screening with temperature checks, wearing personal protective equipment (PPE), and complying with other safety protocols until the number of COVID infections work their way down to acceptable levels. Logically, if these measures are and were effective at preventing the spread of COVID, they will continue to be effective. Thus, no employer can claim an undue hardship by allowing employees to do what they have been doing for over a year, in the alternative to a vaccine.

Liberty Counsel's interpretation of Title VII is also supported by the footnoted, linked press releases from the Equal Employment Opportunity Commission (EEOC)[3] and the U.S. Department of Justice (US DOJ).[4] It is unlawful for employers to force vaccinations on staff and employees holding religious convictions against a vaccine, and to refuse a reasonable accommodation. This goes for healthcare industry employers. In 2018, one hospital paid $89,000 to settle a suit after refusing to accommodate and firing employees who declined flu vaccinations based on their religious beliefs. US DOJ sought compensatory damages on behalf of a nursing home employee against whom Ozaukee County, Wisconsin discriminated.

Singling Out Employees For Individual Questioning or Adverse Action Under the ADA, GINA and Title VII

In interpreting the Americans With Disabilities Act ("ADA"), the **EEOC** has opined that it

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[2] https://www.youtube.com/watch?v=p0zCEiGohJs&list=PLvrp9iOILTQb6D9e1YZWpbUvzfptNMKx2&index=43. See Minute 1:14:40

[3] https://www1.eeoc.gov//eeoc/newsroom/release/1-12-18.cfm?renderforprint=1

[4] https://www.justice.gov/opa/pr/justice-department-files-lawsuit-against-ozaukee-county-wisconsin-religious-discrimination

is improper to "ask only one employee—as opposed to asking all employees—questions designed to determine if [he] has COVID-19, or require that this employee alone have [his] temperature taken or undergo other screening or testing[.] "If an employer wishes to ask only a particular employee to answer such questions, or to have [his] temperature taken or undergo other screening or testing, the ADA requires the employer to have a reasonable belief based on objective evidence that this person might have the disease."[5] EEOC has also stated that an employer may not "**ask an employee who is physically coming into the workplace whether they have family members who have COVID-19 or symptoms associated with COVID-19,**" as such is a violation of the Genetic Information Nondiscrimination Act (GINA). [6]

The **Occupational Safety and Health Administration** (OSHA) has also recognized that there is **"not evidence that COVID-19 vaccines prevent transmission of the virus from person-to-person,"** and reiterated that employers should not improperly distinguish between employees. [7] (Emphasis added). "The most effective COVID-19 prevention programs … include the following elements:"

> 15. ***Not distinguishing between workers who are vaccinated and those who are not:*** Workers who are vaccinated must continue to follow protective measures, such as wearing a face covering and remaining physically distant, because at this time, there is not evidence that COVID-19 vaccines prevent transmission of the virus from person-to-person. The CDC explains that experts need to understand more about the protection that COVID-19 vaccines provide before deciding to change recommendations on steps everyone should take to slow the spread of the virus that causes COVID-19.[8] (Emphasis original and added).

On May 22, 2021, OSHA's reversed the following guidance regarding whether adverse reactions experienced by employees who take the shot under certain conditions or arrangements are recordable on OSHA's recordkeeping log[9]:

> **If I require my employees to take the COVID-19 vaccine as a condition of their employment, are adverse reactions to the vaccine recordable?**
> If you require your employees to be vaccinated as a condition of employment (i.e., for work-related reasons), ***then any adverse reaction to the COVID-19 vaccine is work-related***. The adverse reaction is recordable if it is a new case under 29 CFR 1904.6 and meets one or more of the general recording criteria in 29 CFR 1904.7.[10] (Emphasis added).
>
> **I do not require my employees to get the COVID-19 vaccine. However, I do recommend that they receive the vaccine and may provide it to them or make arrangements for them to receive it offsite. If an employee has an adverse reaction to the vaccine, am I required to record it?**
> No. Although adverse reactions to recommended COVID-19 vaccines may be recordable under 29 CFR 1904.4(a) if the reaction is: (1) work-related, (2) a new case, and (3) meets one or more of the general recording criteria in 29 CFR 1904.7, OSHA is exercising its enforcement discretion to only require the recording of adverse effects to required vaccines at this time. ***Therefore, you do not need to record adverse effects from COVID-19 vaccines that you recommend, but do***

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[5] https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws
[6] *Id.*
[7] https://www.osha.gov/coronavirus/safework#role-employers-workers
[8] *Id.*
[9] https://www.osha.gov/coronavirus/faqs#worker
[10] https://www.osha.gov/coronavirus/faqs#vaccine

> ***not require***. (Emphasis added).
>
> ***Note that for this discretion to apply, the vaccine must be truly voluntary***. For example, an employee's choice to accept or reject the vaccine cannot affect their performance rating or professional advancement. An employee who chooses not to receive the vaccine ***cannot suffer any repercussions from this choice. If employees are not free to choose whether or not to receive the vaccine without fearing adverse action, then the vaccine is not merely "recommended"*** and employers should consult the above FAQ regarding COVID-19 vaccines that are a condition of employment. (Emphasis added).[11]

On May 22, 2021, OSHA's updated FAQ stated as follows:

> Are adverse reactions to the COVID-19 vaccine recordable on the OSHA recordkeeping log?
>
> DOL and OSHA, as well as other federal agencies, are working diligently to encourage COVID-19 vaccinations. OSHA does not wish to have any appearance of discouraging workers from receiving COVID-19 vaccination, and also does not wish to disincentivize employers' vaccination efforts. As a result, OSHA will not enforce 29 CFR 1904's recording requirements to require any employers to record worker side effects from COVID-19 vaccination through May 2022. We will reevaluate the agency's position at that time to determine the best course of action moving forward.[12]

Finally, questioning employees (much less taking adverse employment action against them) on the basis of church membership or church attendance potentially violates not only the ADA, but also Title VII, which prohibits discrimination based on religious worship or religious practices engaged in by the employee outside the workplace.

Conclusion

There are strong protections under federal law for persons who wish to decline the current EUA-authorized COVID vaccines. Neither government nor private employers may force anyone to receive any of the COVID injections.

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[11] *Id.*

[12] https://www.osha.gov/coronavirus/faqs#collapse-vaccine